THE DRUGS ACT, 1940 (XXIII OF 1940).

G. N., G. D., No. 4/21/33 (1), dated 26th March 1947 (B. G., Pt. I, p. 1039). S. 1 (3)

In exercise of the powers conferred by sub-section (*3*) of section 1 of the Drugs Act, 1940 (XXIII of 1940), the Government of Bombay is pleased to appoint the 1st April 1947 as the date from which Chapter IV of the said Act, except sub-clause (*iii*) of clause (*a*) of section 18, shall take effect in the State of Bombay.

G. N., H. & L. G. D., No. 4121/33, dated 15th October 1948 (B. G., Pt. IV-A, p. 412). S. 1 (3)

In exercise of the powers conferred by sub-section (*3*) of section 1 of the Drugs Act, 1940 (XXIII of 1940), the Government of Bombay is pleased to appoint the 1st April 1949 as the date from which sub-clause (*iii*) of clause (*a*) of section 18 of the said Act shall take effect in the State of Bombay.

G. N., L. S. G. & P. H. D., No. 4121/33, dated 25th June 1951 (B. G., Pt. IV-A, p. 280). S. 16 (2)

Whereas the Government of Bombay in its Notification of the Local Self-Government and Public Health Department, No. 4121/33, dated the 30th October 1950, has given notice of its intention to amend the Schedule to the Drugs Act, 1940 (XXIII of 1940), in the manner specified therein ;

Now, therefore, in pursuance of sub-section (*2*) of section 16 of the Drugs Act, 1940 (XXIII of 1940), the Government of Bombay is pleased to amend with effect from the 19th June 1951 the Schedule to the said Act for the purposes of Chapter IV thereof as follows, namely :—

In the Schedule to the Drugs Act, 1940 (XXIII of 1940), in column 2, in the entry against item 4, for the words " latest edition of the British Pharmacopoeia " the words " current edition for the time being of the British Pharmacopoeia " shall be substituted.

G. N., G. D., No. 4121/33 (2), dated 26th March 1947 (B. G., Pt. I, p. 1039). S. 18

In exercise of the powers conferred by section 18 of the Drugs Act, 1940 (XXIII of 1940), the Government of Bombay is pleased to fix the 1st April 1947 as the date for the purposes of sub-clauses (*i*), (*ii*), (*iv*) and (*v*) of clause (*a*) and clauses (*b*) and (*c*) of the said section 18.

G. N., H. & L. G. D., No. 4121/33 (a), dated 15th October 1948 (B. G., Pt. IV-A, p. 412). S. 18

In exercise of the powers conferred by section 18 of the Drugs Act, 1940 (XXIII of 1940), the Government of Bombay is pleased to fix the 1st April 1949 as the date for the purposes of sub-clause (*iii*) of clause (*a*) of the said section 18.

G. N., L. S. G. & P. H. D., No. 4121/33, dated 27th March 1950 (B. G., Pt. IV-A, p. 130). S. 18

In exercise of the powers conferred by section 18 of the Drugs Act, 1940 (XXIII of 1940), the Government of Bombay is pleased to fix the 1st July 1950 as the date for the purposes of the said section.

G. N., H. & L. G. D., No. 4121/33, dated 15th May 1947 (B. G., Pt. IV-C, p. 246). S. 20

In exercise of the powers conferred by section 20 of the Drugs Act, 1940 (Act No. XXIII of 1940), the Government of Bombay is pleased to appoint the Director, Haffkine Institute, Bombay, as the Government Analyst for the State of Bombay, in respect of ' biological and special products ' and ' other special products ' specified in Schedules C and C (I) to the Bombay Drugs Rules, 1946.

G. N., H. & L. G. D., No. 4121/33, dated 15th September 1947 (B. G., Pt. IV-B, p. 700). S. 20

In exercise of the powers conferred by section 20 of the Drugs Act, 1940 (Act XXIII of 1940), the Government of Bombay is pleased to appoint the following

officers of the Haffkine Institute, Bombay, as Government Analysts for the State of Bombay in respect of biological and 'special products' and other 'special products' specified in Schedules C and C (I) to the Bombay Drugs Rules, 1946 :—

(1) Assistant Director in charge of the Department of Pharmocology.
(2) Associate Pharmacologist, Department of Pharmacology.
(3) Senior Chemist, Department of Pharmacology.
(4) Senior Biochemist, Department of Pharmacology.

S. 20 **G. N., L. S. G. & P. H. D., No. 4121/33, dated 31st August 1950 (B. G., Pt. IV-A, p. 531).**

In exercise of the powers conferred under section 20 of the Drugs Act, 1940 (Act XXIII of 1940), the Government of Bombay is pleased to appoint the Director, Central Drugs Laboratory, Calcutta, as Government Analyst for the State of Bombay for the purpose of the testing of samples of patent and proprietary medicines with undisclosed formulae.

S. 21(1) **G. N., H. & L. G. D., No. 4121/33, dated 4th November 1947 (B. G., Pt. IV-B, p. 809).**

In exercise of the powers conferred by section 21(*1*) of the Drugs Act, 1940 (Act XXIII of 1940), the Government of Bombay is pleased to appoint the Director, Haffkine Institute, Bombay and the Director, King Institute, Guindy, as Inspectors for the State of Bombay under sections 21(*1*) and 22 (*a*) of the Act.

S. 33 **G. N., G. D., No. 4121/33, dated the 26th January 1946 (B. G., Pt. IV-C, p. 163).**

Bombay Drugs Rules, 1946.

Amended by G. N., G. D., No. 4121/33-H, dated 6th July 1948.
Amended by G. N., G. D., No. 4121/33, dated 18th October 1949.
Amended by G. N., G. D., No. 4121/33, dated 24th October 1949.
Amended by G. N., G. D., No. 4121/33, dated 3rd December 1949.
Amended by G. N., G. D., No. 4121/33, dated 24th December 1949.
Amended by G. N., G. D., No. 4121/33, dated 28th December 1949.
Amended by G. N., G. D., No. 4121/33, dated 31st December 1949.
Amended by G. N., G. D., No. 4121/33, dated 14th January 1950.
Amended by G. N., G. D., No. 4121/33, dated 19th January 1950.
Amended by G. N., G. D., No. 4121/33, dated 31st January 1950.
Amended by G. N., G. D., No. 4121/33, dated 20th February 1950.
Amended by G. N., G. D., No. 4121/33, dated 28th March 1950.
Amended by G. N., G. D., No. 4121/33, dated 25th May 1950.
Amended by G. N., G. D., No. 4121/33, dated 3rd June 1950.
Amended by G. N., G. D., No. 4121/33, dated 4th July 1950.
Amended by G. N., G. D., No. 4121/33, dated 15th July 1950.
Amended by G. N., L. S. G. & P. H. D., No. 4121/33, dated 2nd January 1951.
Amended by G. N., L. S. G. & P. H. D., No. 4121/33, dated 17th March 1951.
Amended by G. N., L. S. G. & P. H. D., No. 4121/33, dated 19th April 1952.
Amended by G. N., L. S. G & P. H. D., No. 4121/33, dated 8th November 1952.

In exercise of the powers conferred by section 33 of the Drugs Act, 1940 (XXIII of 1940), the Government of Bombay is pleased to make the following rules, namely :—

THE BOMBAY DRUGS RULES, 1946.

1. *Short title, extent and commencement.*—(1) These Rules may be called the Bombay Drugs Rules, 1946.

(2) They extend to the whole of the State of Bombay.

(3) They shall come into force on such date the State Government may, by notification in the Official Gazette, appoint :

Provided that the State Government may, by the said notification, direct that such of the rules applied to the State of Bombay by rule 2 of these Rules as may

be specified shall take effect in the State only from such later date as the State Government may appoint.

2. *Application of rule 2 and Parts V to XII of the (Central) Drugs Rules, 1945.*—Rule 2 and Parts V to XII of the Drugs Rules, 1945,* including the connected Forms and Schedule, shall apply to State of Bombay as they apply to the State of Delhi ;

Provided that all references in the said Rules to the Central Government, Government or Chief Commissioner shall be deemed to be references to the State Government.

APPENDIX.

THE DRUGS RULES, 1945.

PART I.—PRELIMINARY.

1. *Short title, extent and commencement.*—(1) These Rules may be called the Drugs Rules, 1945.

(2) Parts I to IV extend to the whole of British India, and the remaining Parts to the Chief Commissioners' Provinces of Delhi, Ajmer-Merwara and Coorg.

(3) They shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint :

Provided that the Central Government may, by the said notification, direct that specified rules shall take effect only from such later date as it may appoint.

2. *Definitions.*—In these Rules, unless there is anything repugnant in the subject or context,—

(*a*) "the Act" means the Drugs Act, 1940 (XXIII of 1940) ;

(*b*) "British Pharmacopœia" and "British Pharmaceutical Codex" mean the latest editions of, and include all addenda and supplements for the time being current to those compilations ;

(*c*) "Director" means the Director of the Central Drugs Laboratory ;

(*d*) "Form" means a form set forth in Schedule A ;

(*e*) "Laboratory" means the Central Drugs Laboratory ;

(*f*) "Sale by way of wholesale dealing" means sale to a person who buys for the purpose of selling again ;

(*g*) "Schedule" means a Schedule to these Rules.

PART II.—THE CENTRAL DRUGS LABORATORY.

3. *Functions.*—It shall be the function of the Laboratory—

(*i*) to analyse or test such samples of drugs as may be sent to it under sub-section (*2*) of section 11 or under sub-section (*4*) of section 25 of the Act ;

(*ii*) to grant certificates of registration in respect of patent or proprietary medicines ;

(*iii*) to carry out such other duties as may be entrusted to it by the Central Government or, with the permission of the Central Government, by a Provincial Government after consultation with the Drugs Technical Advisory Board.

4. *Despatch of samples for test or analysis.*—(1) Samples for test or analysis under sub-section (*4*) of section 25 of the Act shall be sent by registered post in a sealed packet, enclosed, together with a memorandum in Form I, in an outer cover, addressed to the Director.

* The Drugs Rules 1945, which the Central Government has made under the Drugs Act, 1940, have been printed as an Appendix to these rules.

(2) The packet, as well as the outer cover, shall be marked with a distinguishing number.

(3) A copy of the memorandum in Form I and a specimen impression of the seal used to seal the packet shall be sent separately by registered post to the Director.

5. *Recording of condition of seals.*—On receipt of the packet, it shall be opened by an officer authorised in writing in that behalf by the Director, who shall record the condition of the seals on the packet.

6. *Report of result of test or analysis.*—After test or analysis, the result of the test or analysis together with full protocols of the tests applied, shall be supplied forthwith to the sender in Form 2.

7. *Fees.*—The fees for test and analysis shall be those specified in Schedule B.

8. *Signature of certificates.*—Certificates issued under these rules by the Laboratory shall be signed by the Director or by an officer authorised by the Central Government by notification in the official Gazette to sign such certificates.

PART III.—Registration of Patent or Proprietary Medicines.

9. *Application for registration of patent or proprietary medicines.*—An application for registration of a patent or proprietary medicine, which is required to be registered under the provisions of the Act shall be made in Form 3 by or on behalf of the manufacturer or by the manufacturer's agent in India to the Director, and shall be accompanied by a sample of the medicine sufficient for test or analysis and by a sealed cover containing a certificate in Form 4 declaring the correct formula of the medicine.

10. *Safe keeping of formulae.*—The sealed cover containing the formula shall be opened by the Director or by an officer authorised in writing by the Director and shall be placed on record in a safe, the key of which shall at all times remain in the personal custody of the Director.

11. *Access to formulae.*—No person other than an officer of the Laboratory authorised in writing by the Director shall have access to a formula deposited in the Laboratory.

12. *Destruction of formulae.*—The formula deposited in the Laboratory shall be destroyed by the Director,—

(*i*) if the connected application for registration is rejected, after the expiry of two years from the date of receipt of the application, or

(*ii*) if the application is granted but the certificate of registration is subsequently cancelled, after the expiry of two years from the date of such cancellation.

13. *Disclosure of information.*—No person on the staff of the Laboratory shall disclose to any other person not on the staff any information relating to the composition of a particular patent or proprietary medicine acquired in the course of his duties in the Laboratory :

Provided that the Director or any other officer authorised by him in this behalf may, with the previous sanction of the Central Government, disclose any information so acquired to the extent necessary for the purposes of a prosecution under the Act.

14. *Analysis of samples.*—On receipt of an application for registration, the Director may cause a sample to be analysed or tested in order to ascertain whether it is in accordance with the certified formula.

15. *Rejection of application.*—(1) If it appears to the Director that the formula does not indicate correctly all potent or poisonous ingredients contained in the medicine, together with an approximate statement of the composition of the medicine or that the labels and wrappers intended to be used do not conform to the provisions of these rules, he shall reject the application for registration and shall inform the applicant of the reasons for rejection and supply him with the full protocols of the tests, if any, applied.

(2) Such rejection shall not debar the applicant from making a fresh application.

16. *Issue of certificate.*—(1) If the Director is satisfied that the formula indicates correctly all potent or poisonous ingredients contained in the medicine together with an approximate statement of the composition of the medicine, and that the labels or wrappers intended to be used conform to the provisions of these rules, he shall cause to be issued a certificate of registration in Form 5 and shall assign to the certificate a registration number.

(2) A certificate of registration shall be valid for a period of three years and may be renewed for periods of three years at a time on an application in Form 6 by or on behalf of the manufacturer or by the manufacturer's agent in India to the Director.

(3) A certificate of renewal of registration shall be in Form 7.

(4) If an application for renewal of a certificate of registration is made to the Director before the expiry of three years or before the expiry of the period for which it has been renewed the certificate shall continue to be valid until orders are passed by the Director on the application for renewal.

(5) Before granting an application for renewal the Director may require the applicant to furnish a sample of the medicine and specimens of the labels and wrappers used therewith and he may reject the application if he is satisfied that the registered formula does not indicate correctly all potent or poisonous ingredients together with an approximate statement of the composition of the medicine or that the labels or wrappers do not conform to the provisions of these rules.

17. *Alteration of composition or name.*—If a manufacturer at any time proposes to alter in any way the composition or name of any medicine for which a certificate of registration has been granted, application shall be made for a fresh certificate of registration by the manufacturer or his agent in accordance with these rules.

18. *Fees.*—A fee of fifty rupees shall be paid with each application for a certificate or renewal of a certificate of registration, and shall in no case be refunded to the applicant.

19. *Copies of certificates.*—Copies of all certificates issued under rule 16 shall be retained in the Laboratory, and may be issued to the manufacturer or his agent on payment of a fee of two rupees for each copy.

20. *Discontinuance of manufacture.*—If the manufacture of any registered patent or proprietary medicine is discontinued, the manufacturer or his agent shall, within six months from the date of such discontinuance, give notice of the fact to the Director.

PART IV.—IMPORT.

21. In this Part—

(*a*) "import licence" means a licence in Form 10 to import drugs specified in Schedules C and C (1);

(*b*) "licensing authority" means the authority appointed by the Central Government to perform the duties of the licensing authority under these rules and includes any person to whom the powers of a licensing authority may be delegated under Rule 22;

(*c*) "licence for examination, test or analysis" means a licence in Form 11 to import small quantities of drugs the import of which is otherwise prohibited, for the purpose of examination, test or analysis.

22. A licensing authority may, with the approval of the Central Government by an order in writing, delegate the power to sign licences and such other powers as may be specified in the order to any other person under his control.

23. *Import Licences.*—An import licence shall be required for the import of any biological or other special product specified in Schedule C or C (1).

24. *Form and manner of application.*—An application for an import licence shall be made to the licensing authority in Form 8 by the manufacturer's agent in British India, and shall be accompanied by a fee of rupees ten and by an undertaking in Form 9 signed by or on behalf of the manufacturer.

25. *Licences for import of drugs manufactured by one manufacturer.*—A single application may be made, and a single licence may be issued, in respect of the import of more than one drug or class of drug manufactured by the same manufacturer.

26. *Conditions of import licence.*—An import licence shall be subject to the following conditions:—

(*i*) the manufacturer shall at all times observe the undertaking given by him or on his behalf in Form 9;

(*ii*) the licensee shall allow any inspector authorised by the licensing authority in that behalf to enter with or without notice any premises where the imported substance is stocked, to inspect the means, if any, employed for testing the substance and to take samples;

(*iii*) the licensee shall on request furnish to the licensing authority from every batch of each substance or from such batch or batches as the licensing authority may from time to time specify, a sample of such amount as the licensing authority may consider adequate for any examination required to be made, and the licensee shall, if so required, furnish full protocols of the tests, if any, which have been applied;

(*iv*) if the licensing authority so directs, the licensee shall not sell or offer for sale any batch in respect of which a sample is, or protocols are, furnished under the last preceding sub-rule until a certificate authorising the sale of the batch has been issued to him by or on behalf of the licensing authority;

(*v*) the licensee shall, on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards of strength, quality and purity prescribed by Chapter III of the Act or the rules thereunder and on being directed so to do, withdraw the remainder of that batch from sale and, so far as may in the particular circumstances of the case be practicable, recall the issues already made from that batch;

(*vi*) the licensee shall maintain a record of all sales by him of substances for the import of which a licence is required, showing particulars of the substance and of the person to whom sold and such further particulars, if any, as the licensing authority may specify and such record shall be open to the inspection of any inspector authorised in that behalf by the licensing authority;

(*vii*) the licensee shall comply with such further requirements, if any, applicable to the holders of import licences, as may be specified in any rules, subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than four months' notice.

27. *Grant of import licence.*—On receipt of an application for an import licence in the form and manner prescribed in rule 24 the licensing authority shall, on being satisfied that, if granted, the conditions of the licence will be observed, issue an import licence in Form 10.

28. *Duration of import licence.*—An import licence shall be in force for a period of two years from the date of issue, unless it is sooner suspended or cancelled:

Provided that if application for a fresh licence be made three months before the expiry of the existing licence the current licence shall be deemed to continue in force until orders are passed on the application.

29. *Suspension and cancellation of import licence.*—If the manufacturer or licensee fails to comply with any of the conditions of an import licence, the licensing authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, suspend or cancel it for such period as it thinks fit, either wholly or in respect of some of the substances to which it relates:

Provided that a person who is aggrieved by the suspension or cancellation of his licence may, within three months of the date of the order, appeal to the district judge of the district in which the right of appeal accrues or if there is no district judge of that district such judicial officer as the Central Government may appoint in this behalf, having jurisdiction whose decision shall be final.

30. *Prohibition of import after expiry of potency.*—No biological or other special product specified in Schedule C or C (1) shall be imported after the dates shown on the label, wrapper or container of the drug as the date up to which the drug may be expected to retain a potency not less than, or not to acquire a toxicity greater than that required, or, as the case may be, permitted, by the prescribed test.

31. *Standards for certain imported drugs.*—No biological or other special product specified in Schedule C or C (1) shall be imported unless it complies with the standards of strength, quality and purity, if any, specified in Schedule F, and the tests prescribed in that Schedule shall be applicable for determining whether any such imported drug complies with the said standards.

32. *Packing and labelling of imported drugs.*—The packing and labelling of all drugs imported under an import licence shall be in conformity with the rules in Parts IX and X and Schedule F.

33. *Import of drugs for examination, test or analysis.*—Small quantities of drugs the import of which is otherwise prohibited under section 10 of the Act may be

imported for the purpose of examination, text or analysis subject to the following conditions :—

(*a*) no drug shall be imported for such purpose except under a licence in Form 11 ;

(*b*) the licensee shall use the substances imported under the licence exclusively for purposes of examination, test or analysis and shall carry on such examination, test or analysis in the place specified in the licence, or in such other places as the licensing authority may from time to time authorise ;

(*c*) the licensee shall allow any inspector authorised by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances are kept, and to inspect the premises, and investigate the manner in which the substances are being used and to take sample thereof ;

(*d*) the licensee shall keep a record of and shall report to the licensing authority the substances imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer ;

(*e*) the licensee shall comply with such further requirements, if any, applicable to the holders of licences for examination, test or analysis as may be specified in any rules subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than one month's notice.

34. *Application for licence for examination, test or analysis.*—(1) An application for a licence for examination, test or analysis shall be made in Form 12 and shall be made or countersigned by the head of the institution in which, or by a proprietor or director of the company or firm by which the examination, test or analysis will be conducted.

(2) The licensing authority may require such further particulars to be supplied as he may consider necessary.

35. *Cancellation of licence for examination, test or analysis.*—(1) A licence for examination, test or analysis may be cancelled by the licensing authority for breach of any of the conditions subject to which the licence was issued.

(2) A licensee whose licence has been cancelled may appeal to the Central Government within three months of the date of the order.

36. *Import of drugs for personal use.*—Small quantities of drugs, the import of which is otherwise prohibited under section 10 of the Act, may be imported for personal use subject to the following conditions :—

(*i*) the drugs shall form part of a passenger's *bona fide* baggage and shall be the property of, and be intended for, the exclusive personal use of, the passenger ;

(*ii*) the drugs shall be declared to the customs authorities if they so direct ;

(*iii*) the quantity of any single drug so imported shall not exceed one hundred average doses :

Provided that the licensing authority may in an exceptional case in any individual case sanction the import of a larger quantity.

37. *Packing of patent or proprietary medicines.*—(1) Patent or proprietary medicines shall be imported in containers intended for retail sale :

Provided that such medicines may be imported otherwise than in containers intended for retail sale by any person who holds a license to import for the purpose of examination, test or analysis or a licence to manufacture for sale or a licence to sell, stock and distribute, if such person has given notice to the licensing authority at any time within the twelve months previous to the date of import of his intention to import drugs under this proviso.

(2) Retail sale includes sale to a hospital, dispensary or other institution.

38. *Statement to accompany imported drugs.*—All consignments of drugs sought to be imported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the names and quantities of the drugs.

39. *Documents to be supplied to the Customs-collector.*—Before drugs for the import of which a licence is not required are imported a declaration signed by or on behalf of the manufacturer or by or on behalf of the importer that the drugs comply with the provisions of Chapter 3 of the Drugs Act, 1940, and the rules thereunder shall be supplied to the Customs-collector.

40. *Procedure for drugs for the import of which a licence is not required.*—(1) If the Customs-collector has reason to doubt whether any drugs, for the import of which a licence is not required comply with the provisions of Chapter III of the Act and rules thereunder he may, and if requested by an officer appointed for this purpose by the Central Government shall, take samples of any drugs in the consignment and forward them to the Director of the laboratory appointed for this purpose by the Central Government and may detain the drugs in the consignment of which samples have been taken until the report of the Director of the said laboratory on such samples is received :

Provided that if the importer gives an undertaking in writing not to dispose of the drugs without the consent of the Customs-collector and to return the consignment or such portion thereof as may be required, the Customs-collector shall make over the consignment to the importer.

(2) If an importer who has given an undertaking under the proviso to sub-rule (1) is required by the Customs-collector to return the consignment or any portion thereof he shall return the consignment or portion thereof within ten days of receipt of the notice.

41. (1) If the Director of the laboratory appointed for the purpose by the Central Government reports to the Customs-collector that the samples of any drug in a consignment are not of standard quality, or that the drug contravenes in any other respect the provisions of Chapter III of the Act or the rules thereunder and that the contravention is such that it cannot be remedied by the importer, the Customs-collector shall communicate the report forthwith to the importer who shall, within two months of his receiving the communication, either export all the drugs of that description in the consignment to the country in which they were manufactured or forfeit them to the Central Government which shall cause them to be destroyed :

Provided that the importer may within fifteen days of receipt of the report make a representation against the report to the Customs-collector, and the Customs-collector shall forward the representation with a further sample to the licensing authority, who after obtaining, if necessary, the report of the Director of the Central Drugs Laboratory, shall pass orders thereon which shall be final.

(2) If the Director of the laboratory appointed for the purpose by the Central Government reports to the Customs-collector that the samples of any drug contravene in any respect the provisions of Chapter III of the Act or the rules thereunder and that the contravention is such that it can be remedied by the importer, the Customs-collector shall communicate the report forthwith to the importer and permit him to import the drug on his giving an undertaking in writing not to dispose of the drug without the permission of the officer authorised in this behalf by the Central Government.

42. *Procedure for drugs imported under licence.*—Drugs for the import of which a licence is required may be allowed to be imported if it is shown to the satisfaction of the Customs-collector that they are covered by a valid import licence granted under these rules.

43. The drugs specified in Schedule D shall be exempt from the provisions of Chapter III of the Act and of the rules made thereunder to the extent, and subject to the conditions, specified in that Schedule.

PART V.—GOVERNMENT ANALYSTS AND INSPECTORS.

44. *Qualifications of Government Analysts.*—A person who is appointed a Government Analyst under the Act shall be a person who—

(*a*) is a graduate in medicine or chemistry of a university recognised for this purpose by the appointing authority and has had not less than three years' post-graduate experience in the analysis of drugs in a laboratory under the control of (*i*) a Government Analyst appointed under the Act, (*ii*) a Chemical Examiner to Government, or (*iii*) a fellow of the Royal Institute of Chemistry of Great Britain (Branch E), or (*iv*) the head of an institution specially approved for the purpose by the appointing authority ; or

(*b*) has a first or second class degree in Pharmaceutical Chemistry or Pharmacy, or a post-graduate degree in Chemistry with Pharmaceutics as a special subject from a university recognised for the purpose by the appointing authority and has had not less than two years' post-graduate experience in the analysis of drugs in a laboratory under the control of (*i*) a Government Analyst appointed under the Act, (*ii*) a Chemical Examiner to Government, or (*iii*) a Fellow of the Royal Institute of Chemistry of Great Britian (Branch E), or (*iv*) the head of an institution specially approved for the purpose by the appointing authority ; or

(*c*) is a Fellow of the Royal Institute of Chemistry of Great Britain (Branch E) :

Provided that for the purpose of examination of items 1 to 7, 11 and 15 in Schedule C the person appointed shall be a graduate in medicine or science of a University recognised for the purpose by the appointing authority who can produce evidence of satisfactory training in physiology, bacteriology, serology and pathology and who has had not less than three years' experience of testing biological products in items 1 to 7, 11 and 15 in Schedule C in an institution approved by Government :

Provided further that for a period of four years from the date on which Chapter IV of the Act takes effect in the State, persons whose qualifications, training and experience are regarded by the appointing authority as affording, subject to such further training, if any, as may be considered necessary, a reasonable guarantee of adequate knowledge and competence may be appointed as Government Analysts :

Provided further that no person shall be appointed for any area who is engaged directly or indirectly in any trade or business connected with the sale of drugs.

45. *Duties of Government Analysts.*—(*i*) The Government Analyst shall cause to be analysed or tested such samples of drugs as may be sent to him by inspectors or other persons under the provisions of Chapter IV of the Act and shall furnish reports of the results of test or analysis in accordance with these rules.

(*ii*) A Government Analyst shall from time to time forward to Government reports giving the result of analytical work and research with a view to their publication at the discretion of Government.

46. *Procedure on receipt of sample.*—On receipt of a package from an Inspector containing a sample for test or analysis, the Government Analyst shall compare the seals on the packet with the specimen impression received separately and shall note the condition of the seals on the package. After the test or analysis has been completed, he shall forthwith supply to the Inspector a report in triplicate in Form 13 of the result of the test or analysis, together with full protocols of the tests applied.

Provided that no protocols of tests shall be supplied in the case of patent and proprietary medicines registered at the Central Drugs Laboratory.

47. *Report of result of test or analysis.*—An application from a purchaser for test or analysis of a drug under section 26 of the Act shall be made in Form 14-A and the report of test or analysis of the drug made on such application shall be supplied to the applicant in Form 14-B.

48. *Fees.*—The fees to be paid by a person submitting to the Government Analyst under section 26 of the Act for test or analysis of a drug purchased by him shall be those specified in Schedule B.

49. *Qualifications of Inspectors.*—A person who is appointed an Inspector under the Act shall be a person who—

(*a*) has a degree in Pharmacy or Pharmaceutical Chemistry or a post-graduate degree in Chemistry with Pharmaceutics as a special subject of a University recognised for this purpose by the appointing authority ; or

(*aa*) holds the Pharmaceutical Chemist's diploma granted by the Pharmaceutical Society of Great Britain ; or

(*b*) is a Member of the Pharmaceutical Society of Great Britain ; or

(*c*) is a graduate in medicine or science of a university recognised for this purpose by the appointing authority and has had at least one year's post-graduate training in a laboratory under (*i*) a Government Analyst appointed under the Act, or (*ii*) a Chemical Examiner, or (*iii*) a Fellow of the Royal Institute of Chemistry of Great Britain (Branch E), or (*iv*) the head of an institution specially approved for the purpose by the appointing authority :

Provided that only those Inspectors who have had not less than three years' experience in the manufacture and testing of substances specified in Schedule C in a laboratory approved for this purpose by the licensing authority, shall be authorized to inspect the manufacture of items mentioned in Schedule C :

Provided further that of a period of four years from the date on which Chapter IV of the Act takes effect in the State persons whose qualifications, training and experience are regarded by the appointing authority as affording, subject to such further training, if any, as may be considered necessary, a reasonable guarantee of adequate knowledge and competence, may be appointed as Inspectors and authorize under the preceding proviso :

Provided further that for the purposes of inspection of retail shops in any specified area any officer of the medical or public health department who is a registered medical practitioner or a graduate in science may be appointed an *ex-officio* Inspector.

50. All Inspectors in a State shall be under the control of an officer appointed in this behalf by the Chief Commissioner (hereafter referred to as the controlling authority).

51. *Duties of Inspectors of premises licensed for sale.*—Subject to the instructions of the controlling authority, it shall be the duty of an Inspector authorized to inspect premises licensed for the sale of drugs—

(1) to inspect not less than twice a year all establishments licensed for the sale of drugs within the area assigned to him ;

(2) to satisfy himself that the conditions of the licences are being observed ;

(3) to procure and send for test or analysis, if necessary, samples of any drugs which he has reason to suspect are being sold or stocked or exhibited for sale in contravention of the provisions of the Act or rules thereunder ;

(4) to investigate any complaint in writing which may be made to him ;

(5) to institute prosecutions in respect of breaches of the Act and rules thereunder ;

(6) to maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of samples and the seizure of stocks, and to submit copies of such record to the controlling authority ;

(7) to make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act ;

(8) when so authorised by the Chief Commissioner, to detain imported packages which he has reason to suspect contain drugs, the import of which is prohibited.

52. *Duties of Inspector specially authorized to inspect the manufacture of drugs.*—Subject to the instructions of the controlling authority, it shall be the duty of an Inspector authorized to inspect the manufacture of drugs—

(1) to inspect not less than twice a year, all premises licensed for the manufacture of drugs within the area allotted to him and to satisfy himself that the conditions of the licence and the provisions of the Act and rules thereunder are being observed ;

(2) in the case of establishments licensed to manufacture products specified in Schedules C and C (1) to inspect the plant and the process of manufacture, the means employed for standardising and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to affect the potency or purity of the product ;

(3) to send forthwith to the controlling authority after each inspection a detailed report indicating the conditions of the licence and provisions of the Act and rules thereunder which are being observed and the conditions and provisions, if any, which are not being observed ;

(4) to take samples of the drugs manufactured on the premises and send them for test or analysis in accordance with these rules ;

(5) to institute prosecutions in respect of breaches of the Act and rules thereunder.

53. *Prohibition of disclosure of information.*—Except for the purposes of official business or when required by a court of law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties.

54. *Form of order not to dispose of stock.*—An order in writing by an Inspector under clause (*c*) of section 22 of the Act requiring a person not to dispose of any stock in his possession shall be in Form 15.

55. *Form of receipt for seized drug.*—A receipt by an Inspector for the stock of any drug seized under clause (*c*) of section 22 of the Act, shall be in Form 16.

56. *Form of intimation of purpose of taking sample.*—Where an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.

57. *Procedure for despatch of sample to Government Analyst*—

(1) The portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under sub-section (*4*) of section 23 of the Act shall be sent by registered post or by hand in a sealed packet, enclosed together with a memorandum in Form 18, in an outer cover addressed to the Government Analyst.

(2) A copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Government Analyst separately by registered post or by hand.

58. *Confiscation of drugs.*—When any person has been convicted under Chapter IV of the Act for contravening the provisions of sub-clause (*i*) of clause (*a*) of section 18 of the Act or of rule 110, the stock of the drug in respect of which the contravention has been made shall be liable to confiscation.

PART VI.—Sale of Drugs.

59. (1) The Chief Commissioner shall appoint licensing authorities for the purposes of this Part for such areas as may be specified.

(2) Applications for licences to sell, stock and exhibit for sale, and distribute drugs shall be made in Form 19 to the licensing authority, and shall be accompanied by a fee of rupees five :

Provided that if the applicant fails to apply for a fresh licence before the expiry of the licence in force, the fee for the fresh licence shall be rupees ten.

(3) A fee of Rs. 2 shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

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60. A licensing authority may with the approval of the Central Government by an order in writing delegate the power to sign licences and such other power as may be specified in the order to any other person under his control.

61. *Forms of licences to sell drugs*—

(1) A licence to sell, stock and exhibit for sale, and distribute drugs other than drugs specified in Schedule C shall be issued in Form 20.

(2) A licence to sell, stock and exhibit for sale and distribute drugs specified in Schedule C shall be issued in Form 21.

62. *Sale at more than one place.*—If drugs are sold or stocked for sale at more than one place, a separate application shall be made, and a separate licence shall be issued, in respect of each such place.

63. *Duration of licences.*—Licences to sell drugs shall, unless sooner suspended or cancelled, be in force for two years from the date of issue :

Provided that if application for a fresh licence is made before the expiry of the period of validity of the licence, the licence shall continue to be in force until orders are passed on the application.

64. *Condition to be satisfied before a licence in Form 21 is granted.*—A licence in Form 21 for the sale of biological and other special products specified in Schedule C shall not be granted unless the authority empowered to issue the licence is satisfied that the premises to be licensed are equipped with proper storage accommodation for preserving the properties of the drugs to which the licence applies.

65. *Conditions of licences.*—Licences in Form 20 and Form 21 shall be subject to the conditions stated therein and to the following general conditions :—

(1) Any drug specified in Schedule E or any preparation containing any such drug and any drug supplied on the prescription of a registered medical practitioner shall, if compounded or made up on the licensee's premises, be compounded or made up by or under the direct and personal supervision of a qualified person.

(2) The supply, otherwise than by way of wholesale dealing, of a drug specified in Schedule E or any preparation containing any such drug, and of any drug supplied on the prescription of a registered medical practitioner shall be effected only by or under the personal supervision of a qualified person :

Provided that this condition shall not apply to the sale of a preparation containing a drug specified in Schedule E supplied otherwise than on the prescription of a registered medical practitioner if the preparation has been made up for sale in a container elsewhere than on the premises and the container has not been opened since the time when the preparation was made up for sale therein.

(3) The supply of any drug on the prescription of a registered medical practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose and the serial number of the entry in the register shall be entered on the prescription. The following particulars shall be entered in the register—

(*a*) serial No. of the entry ;

(*b*) the date of supply ;

(*c*) the name and address of the prescriber ;

(*d*) the name of the patient ;

(*e*) the name of the drug or preparation and the quantity or, in the case of a medicine made up by the licensee, the ingredients and quantities thereof ;

(*f*) if the drug is a drug specified in Schedule C, the name of the manufacturer, the batch number and the date recorded on the container, label, or wrapper as the date up to which the substance may be expected to retain a potency not less than or not to acquire a toxicity greater than, that required or permitted by the prescribed test ;

(*g*) the signature of the qualified person by or under whose supervision the medicine was made up and supplied :

Provided that if the medicine is supplied on a prescription on which the medicine has been supplied on a previous occasion it shall be sufficient if the entry in the register includes a serial number, the date of supply, the quantity supplied and a sufficient reference to an entry in the register recording the dispensing of the medicine on a previous occasion.

(4) The supply of a drug specified in Schedule E or preparation containing any such drug or of a drug specified in Schedule C shall be recorded at the time of supply in a register specially maintained for the purpose in which the following particulars shall be entered :—

(*a*) serial number of the entry ;

(*b*) the date of supply ;

(*c*) the name and address of purchaser ;

(*d*) the name of the drug or preparation and the quantity thereof ;

(*e*) if the drug is a drug specified in Schedule C, the name of the manufacturer and the batch number ;

(*f*) the signature of the person under whose supervision the sale was effected :

Provided that this condition shall not apply to supply on the prescription of a registered medical practitioner or by way of wholesale dealing.

(5) Records shall be maintained of all purchases and sales by way of wholesale dealing of drugs specified in Schedule C and such records shall include the following particulars :—

(*a*) the dates of purchase and sale ;

(*b*) the names and addresses of the concerns from which purchased and the concerns to which sold ;

(*c*) the names of the drugs, the quantities and the batch numbers ;

(*d*) the name of the manufacturer.

Such record shall be preserved for three years from the date of the sale of the drug.

(6) The licensee shall produce for inspection by an inspector appointed under the Act on demand all registers and records maintained under these rules, and shall supply to the inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and rules thereunder have been observed.

(7) Except where otherwise provided in these rules, all registers and records maintained under these rules shall be preserved for a period of not less than two years from the date of the last entry therein.

(8) Notwithstanding anything contained in this rule it shall not be necessary to record any particulars in a register specially maintained for the purpose if the particulars are recorded in any other register maintained under any other law for the time being in force.

(9) Substances specified in Schedule H and preparations containing such substances shall not be sold by retail except on and in accordance with a prescription of a registered medical practitioner ;

Provided that no prescription shall be required for sale or supply to a registered medical practitioner, hospital, infirmary or an institution approved by an order of a licensing authority.

(10) For the purposes of clause (9) a prescription shall—

(*a*) be in writing and be signed by the person giving it with his usual signature and be dated by him ;

(*b*) specify the name and address of the person for whose treatment it is given ;

(*c*) indicate the total amount of the medicine to be supplied and the dose to be taken.

(11) The person dispensing a prescription containing a drug specified in Schedule H shall comply with the following requirements in addition to other requirements of these rules :—

(*a*) the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once ;

(*b*) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals it must not be dispensed otherwise than in accordance with the directions ;

(*c*) at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.

(12) Substances specified in Scheduled E kept in a retail shop or premises used in connection therewith shall be stored—

(*a*) in a cupboard or drawer reserved solely for the storage of poisons ; or

(*b*) in a part of the premises separated from the remainder of the premises and to which customers are not permitted to have access.

(13) Substances specified in Schedule E shall be kept in containers impervious to the poison and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport.

(14) A substance specified in Schedule E sold by retail shall be labelled with the word " Poison " in such language or languages as the Chief Commissioner may prescribe by notification in the *Official Gazette*.

(15) The description " Chemist ", " Druggist ", " Chemist and Druggist ", " Pharmacy ", " Pharmacist ", " Pharmaceutist ", " Dispenser ", " Dispensing Chemist " " Dispensary ", " Pharmaceutical Chemist " or any combination of such words, whether in conjunction with other words or otherwise, shall not be used by the licensee in any advertisement or on any label, signboard or name plate or otherwise in connection with the sale of drugs by retail unless the premises are under the personal supervision of a qualified person.

Explanation.—For the purposes of this Rule, " qualified person " means a person who :—

(*a*) holds a degree or diploma in pharmacy or pharmaceutical chemistry, of an Institution approved by the licensing authority, or

(*b*) is a Member of the Pharmaceutical Society of Great Britain, or

(*c*) has had not less than four years practical experience of dispensing which is in the opinion of the licensing authority adequate, and has been approved by that authority as a qualified person.

66. *Cancellation and suspension of licences*—

(1) The licensing authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provision of the Act or rules thereunder ;

Provided that if such failure or contravention is the consequence of an act or omission on the part of an agent or employee, the licence shall not be cancelled or suspended unless the licensing authority is satisfied :

(*a*) that the act or omission was instigated or connived at by the owner of the business or, is the owner is a firm or company, by a partner of the firm or a director of the company ; or

(*b*) that the owner of the business or an agent or employee of the owner had been guilty of a similar act or omission within twelve months before the date on which the act or omission in question took place and that the owner had, or reasonably ought to have had, knowledge of that previous act or omission ; or

(*c*) if the act or omission was a continuing act or omission, that the owner of the business had or reasonably ought to have had, knowledge of that previous act or omission ; or

(*d*) that the owner of the business had not used due diligence to ensure that the conditions of the licence or the provisions of the Act or the rules thereunder were observed.

(2) A licensee whose licence has been suspended or cancelled may appeal to the district judge of the district in which the right of appeal accrues or if there is no district judge of that district such judicial officer as the Central Government may appoint in this behalf within three months of the date of the order.

67. The warranty referred to in sub-section (*3*), section 19 of the Act shall be either in Form 22 or in Form 23.

PART VII.—Manufacture for Sale.

68. *Manufacture on more than one set of premises.*—If drugs are manufactured on more than one set of premises a separate application shall be made and a separate licence shall be issued in respect of each such set of premises.

69. *Application for licence to manufacture drugs other than, special products.*—(1) Applications for the grant or renewal of licenses to manufacture for sale drugs other than those specified in Schedules C and C (1) shall be made to the licensing authority appointed by the Chief Commissioner for the purposes of this Part (hereafter in this Part referred to as the licensing authority) in Form 24 and shall be accompanied by a fee of rupees twenty.

(2) A fee of Rs. 5 shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

70. *Form of licence to manufacture drugs other than special products.*—Licences to manufacture for sale drugs other than those specified in Schedules C and C (1) shall be issued in Form 25.

71. *Conditions to be satisfied before a licence is granted.*—A licence in Form 25 shall not be granted or renewed unless the licensing autority is satisfied that the

manufacture will be conducted under the active direction and personal supervision of a competent technical staff consisting of at least one person who is—

(1) a graduate in Pharmacy or Pharmaceutical Chemistry of a university recognised by the Central Government for the purposes of this Rule, or

(2) a graduate in science for the purposes of his degree, has studied chemistry as a principal subject and has had at least two years' practical experience in the manufacture of drugs, or

(3) a person whose general training, knowledge of chemistry and practical experience, extending over not less than three years, in the manufacture of drugs are in the opinion of the licensing authority adequate.

72. *Duration of licence.*—A licence in Form 25 shall, unless sooner suspended or cancelled, be in force for a period of two years from the date of issue and may thereafter be renewed for periods of two years at a time :

Provided that if application for renewal is made before the expiry of the period of validity of a licence, the licence shall continue in force until orders are passed on such application.

73. *Certificate of renewal.*—The certificate of renewal of a licence in Form 25 shall be issued in Form 26.

74. *Conditions of licence.*—A licence in Form 25 shall be subject to the conditions stated therein and to the following conditions :—

(*a*) the licensee shall provide and maintain an adequate staff and adequate premises and plant for the proper manufacture and storage of the substances in respect of which the licence is issued ;

(*b*) the licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, of which the licensing authority has given the licensee not less than four months' notice ;

(*c*) the licensee shall allow any inspector authorised by the licensing authority in that behalf to enter, with or without prior notice, any premises where the manufacture of a substance in respect of which the licence is issued is carried on, to inspect the premises and to take samples of the manufactured product ;

(*d*) the licensee shall allow an inspector to inspect all registers and records maintained under these rules and shall supply to the inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and rules thereunder have been observed.

75. *Form of application for licence to manufacture drugs specified in Schedules C and C (1).*—(1) Applications for the grant or renewal of licences to manufacture drugs specified in Schedules C and C (1) shall be made to the licensing authority in Form 27 and shall be accompanied by a fee of rupees twenty and an inspection fee of rupees one hundred.

(2) A fee of Rs. 5 shall be paid for a duplicate copy of a licence issued under this rule, if the original is defaced, damaged or lost.

76. *Form of licence to manufacture drugs specified in Schedules C and C (1).*—Licences to manufacture for sale drugs specified in Schedules C and C (1) shall be issued in Form 28.

77. *Duration of licence.*—A licence in Form 28 shall, unless sooner cancelled or suspended, be in force for a period of two years from the date of issue, and may thereafter be renewed for periods of two years at a time :

Provided that if application for renewal is made before the expiry of the period of validity of a licence, the licence shall continue in force until orders are passed on the application.

78. *Conditions of licence.*—A licence in Form 28 shall be subject to the special conditions, if any, set out in Schedule F which relate to the substance in respect of which the licence is granted and to the following general conditions :—

(*a*) (*i*) the licensee shall provide and maintain an adequate staff and adequate premises and plant for the proper manufacture and storage of the substances in respect of which the licence is issued ; (*ii*) without prejudice to the generality of the foregoing requirement, every holder of a licence who for any purpose engages in the culture or manipulation of pathogenic spore-bearing micro-organisms shall provide to the satisfaction of the licensing authority separate laboratories and utensils and apparatus required for the culture or manipulation of such micro-organisms, the laboratories, utensils and apparatus so provided not being used for the manufacture of any other substance ;

(*b*) the licensee shall either (*i*) provide and maintain an adequate staff and adequate premises and plant for carrying out such tests of the strength, quality and purity of the substance as may be required to be carried out by him under the provisions of Part X of these Rules, including proper housing for animals used for the purpose of such tests, or (*ii*) make arrangements with some institution approved by the licensing authority for such tests to be regularly carried out on his behalf by that institution ;

(*c*) the licensee shall keep records of the details of manufacture of each batch of the substance which is issued for sale and of the application of the tests thereto in such form as to be available for inspection and to be easily identified by reference to the number of the batch as shown on the label of each container, and such records shall be retained in the case of a substance for which a potency date is fixed, for a period of two years from the expiry of such date and in the case of other substances for a period of ten years ;

(*d*) the licensee shall allow any inspector, authorised by the licensing authority in that behalf, to enter, with or without prior notice, any premises where the manufacture is carried on and to inspect the premises, and, in the case of substances specified in Schedules C and C (1), to inspect the plant and the process of manufacture and the means employed for standardising and testing the substances ;

(*e*) the licensee shall allow an inspector authorised by the licensing authority under the provisions of condition (*d*) above to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to such inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and rules thereunder have been observed ;

(*f*) the licensee shall from time to time report to the licensing authority any changes in the expert staff responsible for the manufacture or testing of the substance and any material alterations in the premises or plant used for that purpose which have been made since the date of the last inspection made on behalf of the licensing authority before the issue of the licence ;

(*g*) the licensee shall on request furnish to the licensing authority or such other authority as the licensing authority may direct from every batch of the substance, or from such batch or batches as the licensing authority may from time to time specify, a sample of such amount as the authority may consider adequate for any examination required to be made and the licensee shall, if so required, furnish full protocols of the tests which have been applied ;

(*h*) if the licensing authority so directs, the licensee shall not sell or offer for sale any batch in respect of which a sample is, or protocols are, furnished under the last preceding sub-paragraph until a certificate authorising the sale of the batch has been issued to him by or on behalf of the licensing authority ;

(*i*) the licensee shall on being informed by the licensing authority that any part of any batch of the substance has been found by the licensing authority not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of that batch from sale and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch ;

(*j*) no drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture ;

(*k*) the licensee shall comply with the provisions of the Act and of these Rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, of which the licensing authority has given the licensee not less than four months' notice.

79. *Inspection before grant of licence.*—Before a licence in Form 28 is issued, the licensing authority shall cause the establishment on which the manufacture is proposed to be conducted to be inspected by one or more Inspectors appointed by it for the purpose, and the Inspector or Inspectors shall examine all portions of the premises and the plant and appliances, inspect the process of manufacture intended to be employed and the means to be employed for standardising and testing the substances to be manufactured and enquire into the professional qualifications of the technical staff to be employed.

80. *Report by Inspector.*—The Inspector or Inspectors shall forward to the licensing authority a detailed descriptive report of the result of the inspection.

81. *Procedure of licensing authority.*—

(1) If the licensing authority, after such further enquiry, if any, as he may consider necessary, is satisfied that the requirements of the rules under the Act have been complied with and that the conditions of the licence and the rules under the Act will be observed, he shall issue a licence in Form 28.

(2) If the licensing authority is not so satisfied, he shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a licence can be granted and shall supply the applicant with a copy of the inspection report.

82. *Further application after rejection.*—If within a period of six months from the rejection of an application for a licence the applicant informs the licensing authority that the conditions laid down have been satisfied and deposits an inspection fee of rupees thirty, the licensing authority may, if after causing a further inspection to be made he is satisfied that the conditions for the grant of a licence have been complied with, issue a licence in Form 28.

83. *Renewal.*—On application being made for renewal, the licensing authority may cause an inspection to be made and, if satisfied that the conditions of the licence and the rules under the Act are, and will continue to be, observed, shall issue a certificate of renewal in Form 26.

84. The provisions of this part shall apply to the manufacture of drugs for sale notwithstanding that such drugs are manufactured for sale outside India.

85. *Cancellation and suspension of licences.*—

(1) The licensing authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provision of the Act or rules thereunder.

(2) A licensee whose licence has been suspended or cancelled may appeal to the district judge of the district in which the right of appeal accrues or if there is no district judge of that district such judicial officer as the Central Government may appoint in this behalf within three months of the date of the order.

PART VIII.—MANUFACTURE FOR EXAMINATION, TEST OR ANALYSIS.

86. *Conditions relating to manufacture for examination, test or analysis.*—The provisions of section 18 of the Act shall not apply to the manufacture of any drugs in small quantities for the purpose of examination, test or analysis if the conditions prescribed in this Part are fulfilled.

87. *Labelling.*—Any drug manufactured for the purpose of examination, test or analysis shall be kept in containers bearing labels indicating the purpose for which it has been manufactured.

88. *Labelling of drugs supplied to other persons.*—If any drug manufactured for the purpose of examination, test or analysis is supplied by the manufacturer to any other person, the container shall bear a label on which shall be stated the name and address of the manufacturer, the accepted scientific name of the substance if known, or if not known a reference which will enable the substance to be identified and the purpose for which it has been manufactured.

89. *Licence.*— If the person proposing to manufacture a drug for the purpose of examination, test or analysis does not hold a licence in Form 25 or Form 28 in respect of such drug he shall, before commencing such manufacture, obtain a licence in Form 29.

90. *Form of application.*— An application for a licence in Form 29 shall be made to the licensing authority appointed by the Chief Commissioner for the purposes of this Part (hereafter in this Part referred to as the licensing authority) in Form 30 and shall be made by or countersigned by the head of the institution in which, or a director of the firm or company by which, the substance will be manufactured.

91. *Duration of licence.*—A licence in Form 29 shall, unless sooner cancelled, be in force for a period of one year from the date of issue, and may thereafter be renewed for periods of one year at a time.

92. *Conditions of licence.*—A licence in Form 29 shall be subject to the following conditions :—

(*a*) the licensee shall use the drugs manufactured under the licence exclusively for purposes of examination, test or analysis, and shall carry on the manufacture and examination, test or analysis at the place specified in the licence ;

(*b*) the licensee shall allow any Inspector authorised by the licensing authority in that behalf to enter, with or without notice, the premises where the drugs are manufactured and to satisfy himself that only examination, test or analysis work is being conducted ;

(*c*) the licensee shall keep a record of the quantity of drugs manufactured for examination, test or analysis and of any person or persons to whom the drugs have been supplied ;

(*d*) the licensee shall comply with such further requirements, if any, applicable to the holders of licences in Form 29 as may be specified in any rules subsequently made under the Act and of which the licensing authority has given him not less than one month's notice.

93. *Cancellation of licences.*—

(1) The licensing authority may after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a licence issued under this Part, either wholly or in respect of some of the substances to which it relates if, in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provision of the Act or rules thereunder.

(2) A licensee whose licence has been cancelled may appeal to the district judge of the district in which the right of appeal accrues or if there is no district judge of that district such judicial officer as the Central Government may appoint in this behalf within three months of the date of the order.

PART IX.—LABELLING AND PACKING.

94. *Exemption of certain drugs from certain provisions of this Part.*—

(1) The provisions of this Part shall not apply to a drug sold for export to a place outside India.

(2) The provisions of rules 96 to 101 inclusive shall not apply to a medicine made up ready for treatment, whether after or without dilution, which is supplied on the prescription of a registered medical practitioner by a person licensed under these rules to sell drugs, provided that, if the medicine contains a suostance specified in Schedule E, the following conditions are satisfied :—

(*a*) The medicine shall be labelled with the name and address of the licensee by whom it is supplied.

(*b*) If the medicine is for external application, it shall be labelled in the manner prescribed in rule 98 with the word " Poison " and with the words " for external use only ".

(*c*) If the medicine is for internal use, it shall be labelled with the dose.

(*d*) Condition (3) of the conditions in rule 65 shall be satisfied.

95. *Prohibition of sale or distribution unless labelled.*—Subject to the other provisions of these Rules, no person shall sell or distribute any drug (including a patent or proprietary medicine) unless it is labelled in accordance with these Rules.

96. *Manner of labelling.*—(1) Subject to the other provisions of these Rules, the particulars with which the container of any drug is required to be labelled under this Part shall appear in a conspicuous position on the innermost container in which the drug is packed and on every other covering in which that container is packed :

Provided that when the drug is contained in an ampoule it shall only be necessary, except where otherwise provided in these rules, to label the ampoule itself with (1) the name and quantity of the drug and (2) the name of the manufacturer.

(2) Nothing in these Rules shall be deemed to require the labelling of any transparent cover or of any wrapper, case or other covering used solely for the purpose of packing, transport or delivery.

(3) Where by any provision of these Rules any particulars are required to be displayed on a label on the container, such particulars may, instead of being displayed on a label, be etched, painted, or otherwise indelibly marked on the container :

Provided that, except where outherwise provided in these Rules, the name of the drug or any distinctive letters intended to refer to the drug shall not be etched, painted or otherwise indelibly marked on any glass container other than ampoules.

97. *Labelling of medicines.*—(1) The container of a medicine for internal use made up ready for the treatment of human ailments shall—

(*a*) if it contains a substance specified in Schedule E, and not specified in Schedule G, be labelled with the words " Poison " ;

(*b*) if it contains a substance specified in Schedule G, be labelled with the words " Caution. It is dangerous to take this preparation except under medical supervision ".

(*c*) if it contains a substance specified in Schedule H, it shall be labelled with the words :

'SCHEDULE H DRUG'

Warning.—To be sold by retail on the prescription of a Registered Medical Practitioner only.

(2) The container of an embrocation, liniment, lotion, liquid antiseptic or other liquid medicine for external application, which is made up ready for the treatment of human ailments, shall, if the medicine contains a substance specified in Schedule E, be labelled with the words " Poison. For external use only."

(3) The container of a medicine made up ready for the treatment of animals shall, if the medicine contains a substance specified in Schedule E, be labelled with the words " Poison. For animal treatment only ".

(4) The container of a medicine which is not made up ready for treatment, shall, if the medicine contains a substance specified in Schedule E, be labelled with the word " Poison ".

Explanation.—A medicine shall be deemed to be made up ready for treatment if it is made up and labelled with a dose ready for use, whether after or without dilution.

98. *Manner of labelling.*—The words with which a container of a medicine is required to be labelled under rule 97 shall—

(*a*) if the medicine contains a substance specified in Schedule E, either be in red lettering or be set against a red background, and

(*b*) in all cases shall either be on a separate label or be surrounded by a line within which there shall be no other words except words with which the container is required to be labelled under these rules.

99. *Labelling with the name and address of seller.*—The container of any substance specified in Schedule E, or preparation containing such substance shall be labelled with the name and address of the seller and the address of the premises on which it was sold :

Provided that when the substance or preparation is sold in a container and outer covering, it shall be sufficient if the name and address of the seller appears either on the container or on the outer covering :

Provided further that when the substance or preparation is supplied from a warehouse or depot in the course of wholesale dealing it shall be sufficient if the container is labelled with the seller's principal place of business.

100. *Labelling with the name of substance.*—(1) Subject to the provisions of this rule, the container of any substance specified in Schedule E, or preparation containing such substance shall be labelled with the name of such substance.

(2) For the purpose of this rule, the name of a substance shall be the term under which it is included in Schedule E :

Provided that, where the said term describes a group of substances and not the substance specifically, the name of the substance shall be—

(*a*) if the preparation is included in the British Pharmacopœia or the British Pharmaceutical Codex, one or other of the names or synonyms or abbreviated names set out therein ; or

(*b*) in any other case the accepted scientific name where known, or if not known the name descriptive of the true nature or origin of the substance.

(3) In the case of a preparation included in the British Pharmacopœia or the British Pharmaceutical Codex, or any dilution or admixture of such a preparation, or any surgical dressing for which a standard is prescribed in the British Pharmaceutical Codex, it shall be sufficient, notwithstanding anything in the foregoing sub-rules, to state the name, synonym or abbreviated name used to describe the preparation or surgical dressing in the British Pharmacopœia or the British Pharmaceutical Codex, with the addition of the letters " B.P. " or " B.P.C. ", as the case may be.

101. *Labelling with statement of quantity.*—(1) Subject to the provisions of this rule, the label of the container of any preparation containing not less than 3 per cent. by volume of alcohol, or a substance specified in Schedule E, shall include a statement of the quantity of alcohol or of the said substance contained in the preparation as hereafter provided.

(2) If the preparation contains alcohol, the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished product.

(3) If the preparation contains a substance specified in Schedule E, the quantity shall be stated, in the case of a liquid, in terms of grains or minims per fluid ounce, in the case of a solid, in terms of grains or minims per avoirdupois ounce :

Provided that the quantity may be stated in terms of the matric system :

Provided also that when two or more pills, wafers, tablets, powders, capsules or the like are packed in the same container, the quantity shall be stated in terms of the quantity present in each pill, wafer, tablet, powder, capsule or other unit.

(4) In the case of a preparation containing a substance specified in Schedule I, it shall be sufficient to state on the label the particulars specified in that Schedule.

(5) In the case of a preparation included in the British Pharmacopœia or the British Pharmaceutical Codex or any dilution or admixture of such a preparation, or a surgical dressing for which a standard is prescribed in the British Pharmaceutical Codex the container of which is labelled with the name used to describe the article in the British Pharmacopœia or the British Pharmaceutical Codex with the addition of the letters " B.P." or " B.P.C.", as the case may be, it shall not be necessary to state on the label the proportion of the substance specified in Schedule E contained in the preparation.

102. *Non-Sterile Surgical Ligature and Suture.*—Every container of, and wrapper enclosing surgical ligature or suture other than a ligature or suture offered or intended to be offered for sale as sterile shall bear a label on which are printed or written in a conspicuous manner in indelible red ink the words " Non-sterile surgical ligature (suture)—not to be used for operations upon the human body unless efficiently sterilised and tested for sterility by the processes prescribed by Rules under the Drugs Act, 1940."

103. *Additional provisions for patent or proprietary medicines.*—(1) There shall be printed or written in indelible ink on the outer label of every package containing a registered patent or proprietary medicine the letters "CDL" followed by the registration number of the medicine allotted by the Central Drugs Laboratory; and no other reference to the certificate of registration or to the fact of registration shall be made on any label on the container or any covering in which the container is packed or on any other written matter or advertisement enclosed therein.

(2) The name and address of the manufacture shall be printed on the label of the container of a patent or proprietary medicine.

(3) The true formula or list of ingredients, shall be printed or written in indelible ink on the outer label of every package containing an unregistered patent or proprietary medicine.

104. *Use of letters B. P. and B. P. C.*—The letters "B.P." and "B.P.C." shall be entered on the lable on a drug only for the purpose of indicating that the drug is in accordance with the standard set out in the British Pharmacopæia or the British Pharmaceutical Codex, as the case may be.

105. *Packing of patent or proprietary medicines.*—A patent or proprietary medicine shall be made up in containers intended for retail sale.

106. *Diseases which a drug may not purport or claim to prevent or to cure.*—No drug may purport or claim to prevent or to cure one or more of the diseases or ailments specified in Schedule J, or to procure or assist to procure miscarriage in women or to alter or affect the structure of the human body.

PART X.—SPECIAL PROVISIONS RELATING TO BIOLOGICAL AND OTHER SPECIAL PRODUCTS.

107. *Name of substance.*—If any substance specified in Schedule C is advertised or sold as a proprietary medicine or is contained in a medicine so advertised or sold, the proper name of the substance shall appear on the label in the manner prescribed in this part. For the purpose of this rule, the "proper name" means the proper name stated in Schedule F or if no proper name is stated in Schedule F, the name descriptive of the true nature and origin of the substance.

108. *Containers.*—(1) No substance specified in Schedule C shall be sold or offered for sale unless it has been sealed in a previously sterilized glass container in such manner as will in the opinion of the licensing authority suffice to preclude the access of bacteria:

Provided that in the case of surgical ligature or suture the container may be of some substance other than glass.

(2) When any such substance is issued in liquid form in containers which are sealed in such a manner that portions of the contents can be withdrawn for use on different occasions, the liquid shall contain a sufficient proportion of some antiseptic to prevent the growth of any organism which may be accidentally introduced in the process of removing a portion of the contents of the container.

(3) The container shall comply with such further requirements, if any, as are specified in Schedule F in that behalf.

(4) The licensing authority may in the case of any particular preparation of any such substance dispense with any of the requirements of this Rule or of Schedule F, and may make such additional requirements, as having regard to the nature of the preparation, they may deem necessary.

109. *Labelling.*—(1) Every phial, ampoule or other container of a substance specified in Schedule C shall bear a label on which is printed or written in indelible ink the following particulars and such further particulars, if any, as are specified in Schedule F :—

(*a*) the proper name of the substance in letters not less conspicuous than those in which the proprietary name, if any, is printed or written, and following immediately after or under such proprietary name ;

(*b*) the number of every licence under which the substance or any of its constituents is manufactured or imported, preceded in the case of import licences by the words " Imports Licence " ;

(*c*) a distinctive batch number, that is to say, the number by reference to which the prescribed tests, and details of manufacture of the particular batch from which the substance in the container is taken are permanently recorded and available for inspection ;

(*d*) where a test for potency in units is required by these Rules, a statement of the potency in units defined in terms of relation to the standard preparation specified in Schedule F :

Provided that this clause shall not apply in the case of vaccine lymph or surgical ligature or suture.

(2) The particulars prescribed in clauses (*a*), (*b*) and (*c*) of the preceding sub-rule shall be printed or written in indelible ink either on the label borne by a container of vaccine lymph or on a label or wraper affixed to any packages in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.

(3) The following particulars and such further particulars, if any, as are specified in Schedule F shall be printed or written in indelible ink either on the label borne by the container of any substance specified in Schedule C or on a label or wrapper affixed to any package in which any such container is issued for sale :—

(*a*) the name and address of the manufacturer of the final product ;

(*b*) the date on which the manufacture of the particular batch from which the substance in the container is taken was completed, as defined in Schedule F or, if there is no definition in Schedule F, as hereafter defined in this Rule, and in the case of vaccines prepared from concentrates, the date of completion of the final products and the bottling for issue ;

(*c*) where a test for maximum toxicity is required by these Rules a statement that the substance has passed such a test ;

(*d*) where a test for potency or maximum toxicity is required, the date up to which the substance, if kept under suitable conditions, may be expected to retain a potency not less than that stated on the label of the container, or not to acquire a toxicity greater than that permitted by the test, as the case may be ;

(*e*) where an anticeptic substance has been added, the nature and the percentage proportion introduced ;

(*f*) the precautions necessary for preserving the properties of the contents to the date indicated in sub-paragraph (*d*) of this sub-rule.

(4) For the purposes of clause (*b*) of the last preceding sub-rule the date on which the manufacture of a batch is completed shall be—

(*a*) in cases where a test for potency or toxicity is required by these Rules, or, not being so required, is accepted by the licensing authority as sufficient for the purpose of fixing the date of completion of manufacture, the date on which the test was completed, or the date on which the substance was removed from cold

storage after having been kept at a temperature not exceeding 5°C. continuously for a period not exceeding two years from the time when the last test was completed ;

(*b*) in cases where no such test is required or accepted (*i*) if the substance is a serum obtained from living animals, the earliest date on which any material contributing to the batch was removed from the animal, (*ii*) if the substance was obtained by the growth of organisms on artificial media, the earliest date on which growth was terminated in any of the material contributing to the batch, and (*iii*) if the substance is a brain suspension used in the preparation of carbolished antirabic vaccine, the earliest date on which any brain material contributing to the batch was removed from the passage animal :

Provided that, in cases where no such test is required or accepted, if a batch of the substance (including all materials contributing to this batch) has for a period of not more than three years been kept in cold storage at a temperature not exceeding 5°C. continuously from the earliest practicable date after that on which the material was removed from the animal or on which growth was terminated in the material, as the case may be, the date of removal from cold storage shall be treated as the date on which the manufacture of the batch is completed.

110. *Prohibition of sale of substance after prescribed date.*—No person shall sell, or exhibit for sale any substance specified in Schedule C after the date recorded on the container, label or wrapper as the date up to which the substance may be expected to retain a potency not less than, or not to acquire a toxicity greater than, that required or permitted by the prescribed test, as the case may be :

Provided that a person may at the request of a registered medical practitioner sell after the date aforesaid any such substance (except one that is required to be tested for maximum toxicity) which loses its potency, if he has previously drawn the practitioner's attention to the dates recorded on the container, label or wrapper, and the practitioner is satisfied that the sale is required by the urgency of the case.

111. *Standards.*—Every substance specified in Schedules C and C (1) intended for sale shall conform with the standards of strength, quality and purity specified in these Rules and in Schedule F, and the tests for determining such conformity shall be applied to samples taken from the final product after every manufacturing process has been completed.

112. *Tests for strength and quality.*—The tests, if any, required for determining the strength and quality of each of the substances specified in Schedules C and C (1) shall be those set out in Schedule F.

113. *Tests for sterility.*—The test for sterility in the case of surgical ligature or suture shall be that prescribed in Part X of Schedule F.

114. The following tests for the presence of living aerobic or anaerobic bacteria shall be made by the manufacturer or by some institution approved by the licensing authority for the purpose of carrying out tests on his behalf in the case of—

(*a*) sera and solutions of serum proteins intended for injection ;

(*b*) the bacterial vaccines to which Part I (A) of Schedule F applies ;

(*c*) carbolised antirabic vaccine ;

(*d*) toxins, antigens and mixtures of toxins or antigens with serum which are intended to be used in medical practice for immunizing treatment or for diagnosis by inoculation of the patient ;

(*e*) solutions and suspensions of insulin ;

(*f*) dry preparations of insulin intended for therapeutic use ;

(*g*) preparations of the posterior lobe of the pituitary body intended for use by injection except preparations which, after being sealed in the containers, have been sterilised by heat in a manner satisfactory to the licensing authority ; and

(*h*) any other preparations in a form to the administered parenterally except preparations which, after being sealed in containers, have been sterilised by heat in a manner satisfactory to the licensing authority ;

(*i*) preparations from cultures of pathogenic organisms in a form to be administered orally, which must be sterile :

Provided that—(*i*) in the case of dry preparations of insulin the tests shall be applied with such modifications as the licensing authority considers appropriate ; and (*ii*) if a manufacturer satisfied the licensing authority that he has already in use tests for the presence of living aerobic or anaerobic bacteria in any of the above-named substances, and that these tests, as applied by him, will detect the presence of such bacteria in the substance as ready for issue with a certainty at least equal to that afforded by the application of the tests prescribed by this Part, the licensing authority may approve the use of such tests in the place of the prescribed tests, but in such a case the authority may at any time withdraw such approval and require the manufacturer to carry out the prescribed tests.

115. *Application of tests for sterility.*—The tests shall be applied—

(*a*) to samples taken from each batch of the substance before the operation of filling and sealing the containers in which it is to be issued has commenced ; and

(*b*) to the contents of sample containers when ready for issue.

116. *Amount of samples.*—The samples required to be taken under the last preceding rule shall be taken in the following proportions :—

(*a*) in the case of samples taken from the batch, the quantity taken shall be not less than 0·1 per cent. of the total volume of the batch if the volume is not more than 10 litres, and not less than 10 c.c. if the volume is 10 litres or more, but shall in no case be less than 1 c.c. :

Provided that if at the time when the test is made, the batch is contained in a number of bulk containers, samples in the foregoing proportions shall be taken from each of such bulk containers and be separately tested ;

(*b*) in the case of the contents of sample containers the number of containers taken for test shall be not less than 1 per cent. of the total number filled from the batch if this number is not more than 1,000 and not less than 10 containers if the total number is more than 1,000.

117. *Method of preparing and using media.*—(1) The tests shall be made on fluid media, the quantity of medium contained in each tube or other vessel used in the test being such as to secure that any phenolic antiseptic present in the sample is diluted to less than 0·01 per cent.

When an antiseptic other than a phenolic antiseptic is used to dilution to be employed shall be that approved by the licensing authority.

(2) In the case of a test for aerobic organisms the medium shall consist either of a meat extract with the addition of 1 per cent. of peptone, or of such an equivalent as can be prepared by the tryptic digestion of muscle or any other medium approved by the licensing authority. After the final sterilisation the hydrogen-ion concentration of the medium shall be between the limits represented by pH=7·2 and pH=7·8.

(3) In the case of a test for anaerobic organisms the medium shall consist of a nutrient broth similar to that used in testing for aerobic organisms, with the addition of heat coagulated muscle of an amount sufficient to occupy a depth of not less than 1 centimetre at the bottom of the tube. After the final sterilisation the hydrogen-ion concentration of the medium shall be between the limits represented by pH=7·2 and pH=7·8. Before the test inoculation the medium shall be heated to 100°C. for a period sufficient to free it completely from dissolved oxygen, and then be cooled to 37°C. or lower.

(4) The licensing authority may, at the request of any licensee, authorise the use, for the test prescribed under either sub-rule (2) or (3) of this rule, of any other specified medium or method of using a specified medium, on being satisfied that its use affords equal certainty in the detection of the presence of living aerobic or anaerobic organisms, as the case may be.

118. *Method of testing.*—(1) In the case of samples taken from the batch each sample shall be inoculated into tubes or other vessels containing the media, one-half of the total volume of the sample being used for the aerobic and one-half for the anaerobic test.

(2) In the case of the contents of sample containers the contents of each container shall be subjected to the test for aerobic and the test for anaerobic organisms. When the volume in the container is 2 c.c. or more, 1 c.c. shall be used for each test. When the volume in the container is less than 2 c.c., the contents shall be divided into two approximately equal parts, one part being used for the aerobic and the other for the anaerobic test.

(3) The inoculated tubes shall be incubated at 37°C. for five days and be examined after incubation, permanent records being kept of the examination of each tube.

119. (1) If at this examination no growth of micro-organisms is found in any tube, the sample may be treated as having passed the test.

(2) If at the examination a growth of micro-organisms is visible, further samples may be taken and the tests may be repeated on the further samples so taken; but no container the contents of which form part of the batch shall be issued until such further samples have passed the test. The process of taking samples from the batch for a test may, if necessary, be repeated twice:

Provided that if the same organism is visible in more than one test, the batch shall be treated as not sterile and the material contained in the batch shall not be issued or used as part of a further batch unless and until it has been resterilised and has passed the tests.

120. Notwithstanding anything contained in the last preceding rule in any case where—

(*a*) a substance is required in an emergency by a registered medical practitioner, but the licensee has no filled containers in stock: or

(*b*) a substance which in the opinion of the licensing authority is so unstable in solution that the delay occasioned by the completing of the sterility test on filled containers would render its issue in active form impossible, the licensee may issue the substance from a batch which has already passed the tests for sterility and freedom from abnormal toxicity, without completing the sterility test on the filled containers provided that he complies with the following conditions:—

(*i*) the licensee shall before the issue take samples in the required proportions from the containers into which the batch is filled, and after the required inoculation and incubation shall examine the tubes every day for five days;

(*ii*) if at any examination any growth is visible in any of the tubes, he shall immediately notify the licensing authority.

(*iii*) he shall keep available for inspection a record of all issues made under this rule containing such particulars of the circumstances in which the issue is made as the licensing authority may require.

121. *Test for freedom from abnormal toxicity.*—The following tests for freedom from abnormal toxicity shall in the case of each batch of serum, be made by the licensee or by some institution approved by the licensing authority for the purpose of carrying out the tests on his behalf :—

(*a*) a dose of 0·5 c.c. of the serum shall be injected subcutaneously into a normal mouse and the serum may be treated as having passed the test for freedom from an excess of phenolic antiseptic if the injection does not produce death or serious symptoms within seven days ; and

(*b*) a dose of not less than 5 c.c. of the serum shall be injected subcutaneously or intraperitoneally into a normal guineapig and the serum shall be treated as having passed the test for freedom from other abnormal toxic constituents if the injection does not produce death or serious symptoms within seven days.

122. *Substances specified in Schedule C (1).*—The following provisions shall apply in the case of a substance specified in Schedule C (1) :—

(*a*) The container shall comply with the requirements, if any, specified in Schedule F.

(*b*) There shall be printed or written in indelible ink on the label—(*i*) the proper name of the substance ; (*ii*) the number of the licence under which the substance is manufactured or imported, preceded in the case of import licences by the words "Import Licence"; (*iii*) a batch number, that is to say, the number by reference to which the prescribed tests and details of manufacture of the particular batch from which the substance in the container is taken are permanently recorded and available for inspection ; (*iv*) when a test for potency in units is required by these Rules, a statement of the potency in units defined in terms of relation to the standard preparation specified in Schedule F.

(*c*) The substance shall conform with the standards of strength, quality and purity specified in Schedule F and the tests for determining the strength, quality and purity of the substance shall be those specified in Schedule F.

(*d*) The tests for determining the strength, quality and purity of a substance specified in Schedule F shall be applied to samples taken from the final product after each manufacturing process has been completed.

(*e*) The substance should be stored in a cool place and away from light.

PART XI.—Exemption.

123. The drugs specified in Schedule K shall be exempted from the provisions of Chapter IV of the Act and the rules made thereunder to the extent and subject to the conditions specified in that Schedule.

PART XII.—Standards.

124. (1) Indian Pharmacopoeial list, 1946, the United States Pharmacopœia and the National Formulary of the United States shall be deemed to be prescribed pharmacopœias for the purpose of the schedule to the Act.

(2) For drugs for which no standards of identity, purity and strength are specified in the latest edition of the British Pharmacopœia but are specified in the British Pharmaceutical Codex the standards shall be those given in the British Pharmaceutical Codex.

(3) For drugs for which no standards of identity, purity and strength are specified in the latest edition of the British Pharmacopœia or in the British Pharmaceutical Codex but are specified in the earlier editions of the British Pharmacopœia the standards of identity, purity and strength for these drugs shall be those occurring in the latest edition of the British Pharmacopœia in which they are given.

SCHEDULE A.

FORM 1.

[See rule 4.]

Memorandum to the Central Drugs Laboratory.

Serial Number.....

To—The Director, Central Drugs Laboratory.....

From .....

I send herewith, under the provisions of section 25 (*4*) of the Drugs Act, 1940, sample(s) of a drug purporting to be.....

.....for test or analysis and request that a report of the result of the test or analysis may be supplied to this Court.

2. The distinguishing number on the packet is.....
3. Particulars of offence alleged,—.....
4. Matter on which opinion is required :—.....
5. A fee of Rs.....has been deposited in Court.

.....

Date..... Magistrate.

FORM 2.

[See rule 6.]

Certificate of test or analysis by the Central Drugs Laboratory.

Certified that the samples, bearing number....., purporting to be a sample of....., received on.....with memorandum No.....dated..... from....., has been tested/analysed and that the result of such test/analysis is as stated below.

2. The condition of the seals on the packet on receipt was as follows :—

.....

*3. In the opinion of the undersigned the sample $\frac{\text{is of standard quality as defined in}}{\text{is not of standard quality as defined}}$ $\frac{\text{the Drugs Act, 1940, and rules thereunder}}{\text{in the Drugs Act, 1940, and rules thereunder for the reason}}$ given below :—

.....,

Director,

Central Drugs Laboratory, or other authorised officer.

Date.....

Details of results of test or analysis with protocols of tests applied.

.....,

Director,

Central Drugs Laboratory, or other authorised officer.

* If opinion is required on any other matter, this paragraph should be suitably amended.

FORM 3.

[See rule 9.]

Application for a certificate of registration of a patent or proprietary medicine.

I hereby apply for a certificate of registration of the patent or proprietary medicine described below :—

(1) Name of medicine (as proposed to be printed on labels and wrappers).....
.....

(2) Trade mark (if any) .....

(3) Name of manufacturer .....

(4) Address of manufacturer .....

(5) Name and address of person applying for registration.....
.....

(6) Purposes for which medicine is to be used.....

(7) Directions for use .....

(8) Proportion by volume of alcohol present.....

(9) If the medicine contains over 3 per cent. of alcohol by volume, name and quantity per fluid ounce of ingredients present which render the medicine unfit for use as an alcoholic beverage.

2. I send herewith a sample of the medicine sufficient for test or analysis and copies of the labels and wrappers intended to be used.

3. I enclose in a sealed cover the formula or list of ingredients with amounts present.

4. A fee of rupees fifty is forwarded herewith.

(Signed) .....

Date.....

FORM 4.

[See rule 9.]

Enclosure to application for a certificate of registration.

I hereby certify that the following formula or list of ingredients of the patent or proprietary medicine to be sold under the name of.....
and manufactured by.....indicates correctly all potent or poisonous substances contained therein together with an approximate statement of the composition of the medicine.

Formula.

(Signed).....

Date.....

FORM 5.

[See rule 16 (1).]

Certificate of registration of a patent or proprietary medicine.

.....having applied for a certificate of registration in respect of the patent/proprietary medicine marketed under the name of.....
.....manufactured by.....of.....
and having deposited with the Central Drugs Laboratory the formula of the said medicine in accordance with the requirements of the Drugs Act, 1940, and the rules thereunder, the said medicine has been registered and allotted the registration number.....this.....day of.....19.....

Director,
Central Drugs Laboratory, or other authorised officer.

Date.....

FORM 6.

[See rule 16 (2).]

Application for renewal of a certificate of registration of a patent or proprietary medicine.

I hereby apply for renewal of the certificate of registration of the patent/proprietary medicine marketed under the name of.....which was registered and allotted the registration number.....on the..... day of.....19.....

(Signed) .....

Date.....

FORM 7.

[See rule 16 (3).]

Certificate of renewal of registration of a patent or proprietary medicine.

The certificate of registration in respect of the patent/proprietary medicine marketed under the name of.....manufactured by..... .....of....., which was registered and allotted the registration number.....on the..... .....day of.....19.....is hereby renewed until the .....day of.....19.....

Director,
Central Drugs Laboratory, or other authorised officer.

Date.....

FORM 8.

[See rule 24.]

Application for a licence to import biological and other special products specified in Schedules C and C (1) to the Drugs Rules, 1945.

I/We.....hereby apply for a licence to import the substances specified below manufactured by..... .....of.....:—

Names of drugs or classes of drugs.

I/We.....enclose herewith an undertaking signed by or on behalf of the manufacturers as required by the Drugs Rules, 1945.

Date..... .....,
Manufacturer's Agent.

FORM 9.

[See rule 24.]

Form of undertaking to accompany an application for an import licence.

Whereas.....of.....intends to apply for a licence under the Drugs Rules, 1945, for the import into British India, of the substances specified below manufactured by us, we,..... of.....hereby give this undertaking that for the duration of the said licence—

(1) the said applicant shall be our agent for the import of the substances into British India ; and as regards the products specified in Schedule C of the Drugs Rules, 1945, the applicant shall be our sole agent for import into British India.

(2) we shall comply with the conditions imposed on a licensee by clauses (*a*) to (*e*) of Rules 78 of the Drugs Rules, 1945 ;

(3) we declare that we are carrying on the manufacture of the substances mentioned in this undertaking at the premises specified below, and we shall from time to time report any change of premises on which the manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories ;

(4) we shall comply with the provisions of Part IX of the Drugs Rules, 1945 ;

(5) every substance manufactured by us for import under licence into British India shall as regards strength, quality and purity conform with the provisions of Chapter III of the Drugs Act, 1940, and of the Drugs Rules, 1945 ;

(6) we shall comply with such further requirements, if any, as may be specified by rules made by the Central Government under the Act and of which the licensing authority has given to the licensee not less than four months' notice.

List of substances.

Particulars of premises where manufacture is carried on.

Date..... Signed by or on behalf of the manufacturer.

FORM 10.

[See rule 27.]

Licence to import biological and other special products specified in Schedules C and C (1) to the Drugs Rules, 1945.

Number of licence.....

.....of.....is/are hereby licensed to import into British India during the period for which this licence is in force the substances specified below manufactured by.....of.....
.....
.....

2. This licence is subject to the conditions prescribed in the Drugs Rules, 1945, and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said Rules.

Names of drugs or classes of drugs to which the licence applies :—

.....,

Date..... Licensing Authority.

FORM 11.

[See rule 33.]

Licence to import drugs for the purposes of examination, test or analysis.

.....of.....is hereby licensed to import from.....the drugs specified below for purposes of examination, test or analysis at.....or in such other place as the licensing authority may from time to time authorize.

2. This licence is subject to the conditions prescribed in the rules under the Drugs Act, 1940.

3. This licence shall unless previously suspended or revoked be in force for a period of one year from the date specified below :—

Names of drugs.	*Quantities which may be imported.*

.....,

Date..... Licensing Authority.

FORM 12.

[See rule 34.]

Application for licence to import drugs for purposes of examination, test or analysis.

I.....resident of .....
.....by occupation .....
hereby apply for a licence to import the drugs specified below for the purposes of examination, test or analysis at.....from.....
and I undertake to comply with the conditions applicable to the licence.

Names of drugs.	*Quantities.*

Date ..... (Signature) .....

FORM 13.

[See rule 46.]

Certificate of test or analysis by Government Analyst under section 25 (1) of the Drugs Act, 1940.

1. Name of Inspector from whom received.....
2. Serial No. and date of Inspector's memorandum.....
3. Number of sample .....
4. Date of receipt .....
5. Name of drug purporting to be contained in the sample.....
6. Condition of seals on the package.....
*7. Result of test or analysis with protocols of tests applied.....

In the opinion of the undersigned the sample referred to above $\frac{\text{is of standard quality}}{\text{is not of standard}}$ as defined in the Drugs Act, 1940, and rules thereunder.
quality as defined in the Drugs Act, 1940 and rules thereunder for the reasons given below.

Date ..... Government Analyst .....

* No protocols of tests applied shall be supplied in respect of patent and proprietary medicines which are registered at the Central Drugs Laboratory.

FORM 14-A.

[See rule 47.]

Application from a purchaser for test or analysis of a drug under section 26 of the Drugs Act, 1940.

1. Full name and address of the applicant.....
2. Occupation .....
3. Name of the drug purporting to be contained in the sample.....
4. Name and full address of the pharmacy or concern where the drug was purchased.
5. Date on which purchased .....
6. Reasons why the drug is being submitted for test or analysis.....

I hereby declare that the drug being submitted for test was purchased by or for me. I further declare that the sample of the drug being sent for test or analysis is exactly as it was purchased and has not been tampered with in any way to reduce its potency.

Date..... (Signed) .....

FORM 14-B.

[See rule 47.]

Certificate of test or analysis by Government Analyst under section 26 of the Drugs Act, 1940.

1. Name of person from whom sample received.....
2. Date of receipt .....
3. Name of drug purporting to be contained in the sample.....
4. Opinion of the Government analyst—The sample referred to above is/is not of standard quality as defined in the Drugs Act, 1940 and rules thereunder.

Date..... Government Analyst.

FORM 15.

[See rule 54.]

Order under section 22 (c) of the Drugs Act, 1940, requiring a person not to dispose of stock in his possession.

Whereas I have reason to believe that the stock of drugs in your possession detailed below contravenes the provisions of section 18 of the Drugs Act, 1940 ; and whereas I have reported the facts to the District/Chief Presidency Magistrate and have been authorised by him to take action under clause (c) of section 22 of the said Act ;

I hereby require you not to dispose of the said stock for a period of..... days from this date.

Date..... Inspector .....

Details of stock of drugs.

Inspector .....

FORM 16.

[See rule 55.]

Receipt for stock of drugs seized under section 22 (c) of the Drugs Act, 1940.

The stock of drugs detailed below has this day been seized by me under the provisions of clause (*c*) of section 22 of the Drugs Act, 1940, from the premises of..... .....situated at .....

Date ..... Inspector .....

Details of drugs seized.

Date..... Inspector .....

FORM 17.

[See rule 56.]

Intimation to person from whom sample is taken.

To.....

I have this day taken from the premises of..... situated at ..... samples of the drugs specified below for the purposes of test or analysis.

Date..... Inspector .....

Details of samples taken.

Date ..... Inspector .....

FORM 18.

[See rule 57.]

Memorandum to Government Analyst.

Serial No. of Memorandum .....

From

To

The Government Analyst

The portion of sample/container described below is sent herewith for test or analysis under the provisions of clause (*i*) of sub-section (*4*) of section 23 of the Drugs Act, 1940.

The portion of sample/container has been marked by me with the following mark :—

Details of portion of sample or container with name of drug which it purports to contain :—

Date..... Inspector.....

FORM 19.

[See rule 59.]

Application for a licence to sell, stock and exhibit for sale and distribute drugs.

I/We.....of.....
hereby apply for a licence to sell by retail/by wholesale drugs other than biological / biological and other special products / and other special products on the premises situated at .....

*2. The sale of drugs will be under the personal supervision of .....
(Name) .....(Qualification).....
(Name) .....(Qualification).....

3. Classes of products to be sold .....

†4. Particulars of storage accommodation for the storage of biological and other special products on the premises referred to above.....

Signature.....

Date.....

FORM 20.

[See rule 61 (1).]

Licence to sell, stock and exhibit for sale and distribute drugs other than biological and special products specified in Schedule C.

..... is hereby licensed to sell, stock and exhibit for sale and distribute on the premises situated at .... drugs other than biological and special products specified in Schedule C to the Drugs Rules, 1945, subject to the conditions specified below and to the provisions of the Drugs Act, 1940, and the rules thereunder.

2. This licence will be in force for two years from the date given below.

‡3. Name(s) of qualified person(s) in charge .....

Date..... Licensing Authority.

---

* To be deleted if drugs will be sold only by wholesale.
† Only required if products requiring cold storage are to be sold.
‡ If the licence is required for wholesale dealings only delete and enter the word "wholesale".

Conditions of licence.

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.

2. The licensee shall comply with the provisions of the Drugs Act, 1940, and the rules thereunder for the time being in force.

3. The licensee shall report forthwith to the licensing authority any change in the qualified staff in charge.

4. No drug in Schedule C (1) shall be sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it has been in the possession of the licensee.

FORM 21.

[See rule 61 (2).]

Licence to sell, stock and exhibit for sale and distribute biological and special products specified in Schedule C.

..... is hereby licensed to sell, stock and exhibit for sale and distribute on the premises situated at .... the biological and special products specified in Schedule C to the Drugs Rules, 1945, subject to the conditions specified below and to the provisions of the Drugs Act, 1940, and the rules thereunder.

2. This licence will be in force for two years from the date given below.

3. Particulars of biological products to be sold .....

*4. Name(s) of qualified person(s) in charge .....

Date..... Licensing Authority.

Conditions of licence.

1. This licence shall be displayed in a prominent place in a part of the premises open to the public.

2. The licensee shall report forthwith to the licensing authority any change in the qualified staff in charge.

3. No drug to which this licence applies shall be sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it has been in the possession of the licensee.

4. If the licensee wants to sell, stock, exhibit for sale or distribute during the currency of the licence, additional products specified in Schedule 'C' not included above, he should apply to the Licensing Authority for the necessary permission. This licence will be deemed to extend to the products in respect of which such permission is given. This permission should be endorsed on the licence by the Licensing Authority.

* If the licence is required for wholesale dealings only delete and enter the word "wholesale".

FORM 22.

[See rule 67.]

General Warranty under section 19 (3) of the Drugs Act, 1940.

I, ... being a person resident in India† carrying on business at ..... under the name of .....* (and being an agent of .....), do hereby give this warranty that the goods or classes of goods hereunder described as sold by me, do not contravene in any way the provisions of section 18 of the Drugs Act, 1940.

Date..... (Signed).....

List of goods or classes of goods.

(Signed) .....

FORM 23.

[See rule 67.]

Specific Warranty under section 19 (3) of the Drugs Act, 1940.

I,.....being a resident of India† carrying on business at.....under the name of..... .....*(and being an agent of.....), do hereby give this warranty that the goods, hereunder specified and contained in the bill of sale, invoice, bill of lading or other documents describing the goods referred to herein, do not contravene in any way the provisions of section 18 of the Drugs Act, 1940.

Date..... (Signed) .....

List of goods and description of bill of sale, invoice, bill of lading or other document.

(Signed) .....

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* Omit the words in brackets if the warranty is given by the manufacturer and not by an agent.

† "India" means the territory of India excluding the State of Jammu and Kashmir (*vide* s. 3 (*bb*) of Act XXIII of 1940).

FORM 24.

[See rule 69.]

Application for a licence to manufacture drugs other than biological and other special products.

I/We, ...of..... hereby apply for (renewal of) a licence to manufacture on premises situated at..... .....drugs other than drugs specified in Schedules C and C (1) to the Drugs Rules, 1945.

2. Class of drugs to be manufactured.....

3. Names, qualifications and technical experience of technical staff to be employed in the direction and supervision of manufacture and testing.

(Signed) .....

Date.....

NOTE.—The application should be accompanied by a plan of the premises.

FORM 25.

[See rule 70.]

Licence to manufacture drugs other than biological and special products.

Number of licence and year of issue.

.....is hereby licensed to manufacture drugs other than drugs specified in Schedules C and C (1) to the Drugs Rules, 1945, at the premises situated at.....under the direction and supervision of the following expert staff :—

2. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the products manufactured under the licence, subject to the conditions applicable to licences for sale.

3. The licence shall be in force for a period of two years from the date of issue.

4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs Act, 1940.

Signature .....

Designation .....

Date .....

Conditions.

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs Act, 1940.

2. Any change in the expert staff named in the licence shall be forthwith reported to the licensing authority.

FORM 26.

[See rules 73 and 83.]

Certificate of renewal of licence to manufacture drugs.

Certified that the licence No.....granted on the.....
to.....for the manufacture of drugs other than drugs specified in Schedules C and C (1) to the Drugs Rules, 1945 / the undermentioned drugs, being drugs specified in Schedules C and C (1) to the Drugs Rules, 1945 at the premises situated at .....
.....has been renewed for a period of two years from the .....

* *Names of drugs* (each substance to be separately specified).

2 Names of approved expert staff :—

Signature .....

Date ..... Designation .....

FORM 27.

[See rule 75.]

Application for grant, or renewal of a licence to manufacture biological and other special products.

I/We.....hereby apply for (renewal of) a licence to manufacture on premises situated at..... the undermentioned drugs, being drugs specified in Schedules C and C (1) to the Drugs Rules, 1945.

Names of drugs (each substance to be separately specified).

2. The names, qualification and technical experience of the expert staff to be responsible for the manufacture or testing of the abovementioned substances are as follows :—

3. The premises and plant are ready for inspection / will be ready for inspection on.....

Signature .....

Date .....

NOTE.—The application shall be accompanied by a plan of the premises.

* To be completed only in the case of drugs specified in Schedules C and C (1) to the Drugs Rules, 1945.

FORM 28.

[See rule 76.]

Licence to manufacture biological and other special products.

Number of licence and year of issue .....
is hereby licensed to manufacture at the premises situated at .....
the following drugs, being drugs specified in Schedules C and C (1) to the Drugs Rules, 1945 :—

Names of drugs :—

2. Names of approved expert staff :—

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the products manufactured under the licence, subject to the conditions applicable to licences for sale.

4. The licence will be in force for a period of two years from the date of issue.

5. The licence is subject to the condition stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs Act, 1940.

Signature .....

Date of issue

Designation .....

Conditions.

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs Act, 1940.

2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule C or C (1) not included above he should apply to the licensing authority for permission to manufacture the drug. This licence will be deemed to authorise the manufacture of any drug in respect of which such permission has been given.

3. Any change in the expert staff shall be forthwith reported to the licensing authority.

FORM 29.

[See rule 89.]

Licence to manufacture drugs for purposes of examination, test or analysis.

.....of.....
is hereby licensed to manufacture the drugs specified below for purposes of examination, test or analysis at .....
.....

2. This licence is subject to the conditions prescribed in Part VIII of the Drugs Rules, 1945.

3. This licence shall be in force for one year from the date specified below

Names of Drugs.

Date..... Licensing Authority.....

FORM 30.

[See rule 90.]

Application for licence to manufacture drugs for purposes of examination, test or analysis.

I ..... of .....
..... by occupation .....
hereby apply for a licence to manufacture the drugs specified below for purpose of examination, test or analysis at ..... and I undertake to comply with the conditions applicable to the licence.

Names of Drugs.

Date ..... Signature.....

SCHEDULE B.

[See rules 7 and 48.]

Fees for test or analysis by the Central Drugs Laboratory or the Government Analyst.

I.—*Fees for Biological Assay and Certification.*

	Rs.
Digitalis powder ..	24
Digitalis Tincture ..	24
Strophanthin ..	24
Strophanthus Tincture ..	24
Pituitary (Posterior Lobe) Extract ..	24
Adrenaline and preparations of Adrenaline ..	32
Penicillin ..	25
Insulin ..	*32 to 40
Thyroid ..	32
Sex gland preparations :—	
Ovarian ..	*32 to 64
Luteal ..	
Orchis ..	
Vitamin preparations :—	
Vitamin A ..	*32 to 64
Vitamin B ..	
Vitamin C	
Vitamin D (Calcifero) .	
Cod Liver Oil ..	

	Rs.
Organic Arsenic Compounds—	
Neoarsphenamine, Sulpharsphenamine and Allied Products	*40 to 64
Non-organic antimony compounds ..	24
Toxicity tests for organic Antimony Compounds and other Compounds in experimental stage .	16
Sera and vaccines :—	
(*i*) Sera—	
(*a*) Determination of exact titre ..	75
(*b*) Determination that a sample is up to titre specified ..	50
(*ii*) Vaccines :—	
(*a*) Examination in which an animal test is employed ..	50

* The exact amount of fee will be determined in each case by the Director or the Government Analyst, as the case may be.

I—*Fees for Biological Assay and Certification*—contd.

	Rs.
(*b*) Examination in which an animal test is not employed ..	25
(*iii*) Bacteriological test of disinfectants and antiseptics ..	45
(*iv*) Tests for sterility ..	12

II.—*Fees for examination of drugs according to pharmacopœial tests except where a biological assay is necessary.*

	Rs.
Qualitative test only ..	20
Complete qualitative and quantitative tests ..	30

III.—Fees for the determination of the saponification value, the acid value, the iodine value, the refractive index or the density of an oil or a fat. 10

For each additional determination .. 5

SCHEDULE C.

[See rules 23, 61 and 76 and Part X.]

Biological and special products.

1. Sera.
2. Solution of serum proteins intended for injection.
3. Vaccines for parenteral injections.
4. Toxins.
5. Antigens.
6. Antitoxins.
7. Neo-arsphenamine and analogous substances used for the specific treatment of infective diseases.
8. Insulin.
9. Pituitary (Posterior Lobe) Extract.
10. Adrenaline and Solutions of Salts of Adrenaline.
11. Penicillin preparations of Penicillin for parenteral administration.
12. Streptomycin.
13. Any other preparations in a form to be administered parenterally.
14. Sterilised surgical ligature and sterilised surgical suture.
15. Bacteriophages.

SCHEDULE C (1).

[See rules 23, 61 and 76.]

Other special products.

1. Drugs belonging to the Digitalis group and the preparations thereof not in a form to be administered parenterally.
2. Ergot and its preparations not in a form to be administered parenterally.
3. Adrenaline and the preparations thereof not in a form to be administered parenterally.
4. Fish liver oil.
5. Vitamins and the preparations thereof not in a form to be administered parenterally.
6. Liver extract and the preparations thereof not in a form to be administered parenterally.
7. Hormones and the preparations thereof not in a form to be administered parenterally.
8. Vaccines not in a form to be administered parenterally.
9. Preparations containing Penicillin not in a form to be administered parenterally.

SCHEDULE D.

[See rule 43.]

Class of drugs.	Extent and conditions of exemption.
1. Substances not intended for medical use.	All provisions of Chapter III of the Act and rules thereunder subject to the condition that if the substance is imported in bulk, the importer shall certify that the substance is imported for non-medicinal uses, and if imported otherwise than in bulk, each container shall bear a label indicating that the substance is not intended for medicinal use or is intended for some purposes other than medicinal use or is of commercial quality.
2. Biological and other special products referred to in Schedule C intended to be used solely for veterinary purposes.	All provisions of Chapter III of the Act and rules thereunder subject to the condition that each container shall bear a label indicating that the substance is for veterinary use only.
3. Patent or proprietary medicine intended to be used solely for veterinary purposes.	All provisions of Chapter III of the Act and rules thereunder subject to the condition that the description on the label or container shall indicate that the medicine is intended for administration to animals.

SCHEDULE E.

[See rules 65 and 97.]

List of poisons.

Acetanilide ; Alkyl acetanilides.

Aconite, roots of.

Alkaloids, the following ; their salts, simple or complex.

Acetyldihydrocodeinone ; its esters.

Aconite, alkaloids of, except substances containing less than 0·02 per cent. of the alkaloids of aconite.

Apomorphine, except substances containing less than 0·2 per cent. of apomorphine.

Atropine, except substances containing less than 0·15 per cent. of atropine.

Belladonna, alkaloids of, except substances containing less than 0·15 per cent. of the alkaloids, of belladonna calculated as hyoscyamine.

Benzoylmorphine.

Benzylmorphine.

Brucine, except substances containing less than 0·2 per cent. of brucine.

Calabar bean, alkaloids of.

Coca, alkaloids of, except substances containing less than 0·1 per cent. of the alkaloids of coca.

Cocaine, except substances containing less than 0·1 per cent. of cocaine.
Codeine, except substances containing less than one per cent. of codeine.
Colchicine, except substances containing less than 0·5 per cent. of colchicine.
Coniine, except substances containing less than 0·1 per cent. of coniine.
Cotarnine, except substances containing less than 0·2 per cent. of cotarnine.
Curarine.
Diamorphine (Diacetylmorphine hydrochloride).
Dihydrocodeinone ; its esters.
Dihydroxycodeinone ; its esters.
Dihydromorphine ; its esters.
Dihydromorphinone ; its esters.
Ecgonine ; except substances containing less than 0·1 per cent. of ecgonine, its esters.
Emetine, except substances containing less than one per cent. of emetine.
Ephedra, alkaloids of, except substances containing less than one per cent. of the alkaloids of Ephedra.
Ergot, alkaloids of.
Ethylmorphine, except substances containing less than 0·2 per cent. of ethylmorphine.
Gelsemium, alkaloids of, except substances containing less than 0·1 per cent. of the alkaloids of gelsemium.
Homatropine, except substances containing less than 0·15 per cent. of homatropine.
Hyoscine, except substances containing less than 0·15 per cent. of hyoscine.
Hyoscyamine, except substances containing less than 0·15 per cent. of hyoscyamine.
Jaborandi, alkaloids of, except substances containing less than 0·5 per cent. of the alkaloids of jaborandi.
Lobelia, alkaloids of, except substances containing less than one per cent. of the alkaloids of lobelia.
Morphine, except substances containing less than 0·2 per cent. of morphine calculated as anhydrous morphine.
Nicotine.
Papaverine, except substances containing less than one per cent. of papaverine.
Pomegranate, alkaloids of, except substances containing less than 0·5 per cent. of the alkaloids of pomegranate.
Quebracho, alkaloids of.
Sabadilla, alkaloids of, except substances containing less than one per cent. of the alkaloids of sabadilla.
Solanaceous alkaloids, not otherwise included in this List, except substances containing less than 0·15 per cent. of solanaceous alkaloids calculated as hyoscyamine.
Stavesacre, alkaloids of, except ointments, lotions for external use and substances containing less than 0·2 per cent. of the alkaloids.
Strychnine, except substances containing less than 0·2 per cent. of strychnine.
Thebaine, except substances containing less than one per cent. of thebaine.
Veratrum, alkaloids of, except substances containing less than one per cent. of the alkaloids of veratrum.
Yohimba, alkaloids of.
Allylisopropylacetylurea.
Amidopyrine ; its salts.

Amino-alcohols, esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids, except in substances containing less than ten per cent. of esterified amino-alcohols.

Ammonia, except substances containing less than 5 per cent. weight in weight, of ammonia.

Amphetamine (beta-aminopropylbenzene), its salts, its N-alkyl derivatives, their salts, beta-amino-iso-propy benzene, its salts, its N-alkyl derivatives, their salts, except when present in inhalers provided that the poison is absorbed in inert solid material within the inhaler.

Amyl nitrite.

Antimony, chlorides of; oxides of antimony; sulphides of antimony; antimonates; antimonites; organic compounds of antimony. Preparations of antimony, except substances containing less than the equivalent of one per cent. of antimony trioxide.

Arsenic, halides of; oxides of arsenic; sulphides of arsenic; arsenates; arsenites; acetoarsenites; thioarsenates; organic compounds of arsenic. Preparations of arsenic, except substances containing less than the equivalent of 0·01 per cent. of arsenic trioxide.

Barbituric acid, its salt; derivatives of barbituric acid; their salts; compounds of barbituric acid, its salts, its derivatives, their salts, with any other substance.

Barium, salts of, other than barium sulphate.

Butylchloral hydrate.

Cannabis (the dried flowering or fruiting tops and leaves of Cannabis sativa Linn); the resin of cannabis, extracts of cannabis; tinctures of cannabis; cannabin tannate.

Cantharidates, except substances containing less than the equivalent of 0·01 per cent. of cantharidin.

Cantharidin, except substances containing less than 0·01 per cent. of cantharidin.

Chloral formamide.

Chloral hydrate.

Chloroform, except substances containing less than 10 per cent. of Chloroform.

Creosote from wood.

Croton, oil and seeds of.

Datura, seeds and leaves of; preparations of datura, except substances containing less than 0·15 per cent. of the alkaloids of datura calculated as hyoscine.

Diaminodiphenylsulphone, its salts and derivatives.

Digitalis, glycosides of, except substances containing less than one unit of activity (as defined in the British Pharmacopœia) in two grammes of the substance.

Dinitrocresols; dinitronaphthols; dinitrophenols; dinitrothymols.

Elaterin.

Ergot (the sclerotia of any species of Claviceps); extracts of Ergot; tinctures of Ergot.

Erythrityl tetranitrate.

Formaldehyde, except substances containing less than 5 per cent. Formaldehyde.

Glyceryl trinitrate (nitroglycerine).

Guanidines, the following; polymethylene diguanidines, dipara-anisylphenetyl guanidine.

Hydrochloric acid, except substances containing less than 9 per cent. weight in weight, of hydrochloric acid.

Hydrocyanic acid, except substances containing less than 0·1 per cent. of hydrocyanic acid (HCN); cyanides, except substances containing less than the equivalent of 0·1 per cent. weight in weight, of hydrocyanic acid (HCN); double cyanides of mercury and zinc.

Hydrofluoric acid; potassium fluoride; sodium fluoride; sodium silicofluoride.

Insulin.

Lead acetates: compounds of lead with acids from fixed oils.

Mannityl Hexanitrate.

Mercuric chloride or mercuric ammonium chlorides; except substances containing less than one per cent. of mercuric chloride; mercuric iodide, except substances containing less than two per cent. of mercuric iodide; nitrates of mercury, except substances containing less than the equivalent of three per cent. weight in weight of mercury (Hg.); potassio-mercuric iodides, except substances containing less than the equivalent of one per cent. of mercuric iodide; organic compounds of mercury, except substances containing less than the equivalent of 0.2 per cent. weight in weight, of mercury (Hg.); mercuric oxycyarides; oxides of mercury.

Nitric acid, except substances containing less than 9 per cent. weight in weight, of nitric acid.

Nitrobenzene.

Nitrophenols, ortho, meta or para.

Nux Vomica, seeds of; preparations of nux vomica, except substances containing less than 0·2 per cent. of the alkaloids of nux vomica.

Oil of Savin.

Opium, except substances containing less than 0·2 per cent. of morphine calculated as anhydrous morphine.

Orthocaine; its salts.

Ouabain.

Oxalic acid; metallic oxalates other than potassium quadroxalate.

Oxycinchoninic acid, derivatives of; their salts; their esters.

Para-amino-benzene-sulphonamide; its salts, derivates of para-amino-benzene sulphonamide having any of the hydrogen atoms of the para-amino group or of the sulphamido group substituted by another radical; their salts.

Para-amino-benzoic acid; esters of; their salts.

Percain.

Pethidine Hydrochloride.

Phenetidylphenacetin.

Phenols, that is, any member of the series of phenols of which the first member is phenol and of which the molecular composition varies from member to member by one atom of carbon and two atoms of hydrogen.

Phenylcinchoninic acid, salicyl-cinchoninic acid; their salts; their esters.

Phenylene diamines; toluene diamines; other alkylated benezene diamines, their salts.

Phenylethylhydantoin; its salts; its acyl derivatives; their salts.

Phosphorus yellow.

Picric acid, except substances containing less than 5 per cent. Picric acid.

Picrotoxine.

Pituitary gland, the active principles of.

Potassium hydroxide, except substances containing less than 12 per cent., weight in weight, of potassium hydroxide.

Procaine, salts of.

Sodium hydroxide, except substances containing less than 12 per cent., weight in weight, of sodium hydroxide.

Sulphonal ; alkyl sulphonals.

Sulphuric acid, except substances containing less than 9 per cent., weight in weight, of sulphuric acid.

Strophanthus, glycosides of strophanthus.

Suprarenal gland, the active principles of ; their salts.

Thallium, salts of.

Thyroid gland, the active principles of ; their salts.

Tribromethyl alcohol.

Zinc Chloride.

SCHEDULE F.

[See rule 78 and Part X.]

PART I.—VACCINES.

(A) PROVISIONS APPLICABLE TO THE PRODUCTION OF BACTERIAL VACCINES.

1. *Definition.*—(1) This Part of this Schedule applies to vacterial vaccines made from any micro organism pathogenic to man or other animal and to vaccines made from other micro-organism which have any antigenic value.

(2) For the purposes of this Part of this Schedule a bacterial vaccine means a sterile suspension of a killed culture of the micro-organism from which the vaccine derives its name or a sterile extract or derivative of a micro-organism which has been prepared from a genuine culture of the micro-organism.

2. *Staff of Establishment.*—The establishment where vaccines are prepared must be under the complete direction and control of a competent expert in bacteriology, who must be assisted by a staff adequate for carrying out the tests required during the preparation of the vaccines and in connection with the finished products.

3. *Proper Name.*—The proper name of any vaccine shall be the name of the micro-organism from which it is made, followed by the word "vaccine" unless this Schedule otherwise provides or, if there is no special provision in this Schedule, some other name is approved by the licensing authority : Provided that in the case of the undermentioned preparations the proper name of the vaccine may be as follows :—

Anti-cholera vaccine	Anti-plague vaccine ;
Anti-typhoid vaccine	Anti-dysentery vaccine ;
	Whooping cough vaccine.

Antityphoid-paratyphoid (T.A.B.) Vaccine ;

Antityphoid-paratyphoid (A. B. & C.) Vaccine ;

Antityphoid-paratyphoid (A & B.) and Cholera Vaccine ;

4. *Records.*—Cultures used in the preparation of vaccines must, before being manipulated into a vaccine, be thoroughly tested for identity by the generally accepted tests applicable to the particular micro-organism. The permanent records which the licensee is required to keep shall include a record of the original properties and characteristics of the cultures.

5. *Combined Vaccines.*—Vaccines may be issued either singly or combined in any proportion in the same container. In the case of combinations of vaccines a name for the combined vaccine may be submitted by the licensee to the licensing authority, and, if approved, may be used as the proper name of the vaccine.

6. *Labelling.*—(1) The label on the container shall indicate the composition of the vaccine by reference either:—

(*a*) to the number of micro-organisms per c. c.; or

(*b*) to the weight of dried substance of micro-organisms per c. c.; or

(*c*) to the number of micro-organisms or weight of dried substance of micro-organisms used in preparing 1 c.c. of the finished product.

In the case of a combined vaccine the reference to the number of micro-organisms per c. c. or to the weight of dried substance of micro-organism shall distinguish between the several kinds of contributing micro-organisms.

(2) If the vaccine as issued for sale is combined with any substance other than a simple diluent, the exact nature and strength of such substance must be stated on the label.

7. *Tests.*—In the case of any vaccine prepared from a micro-organism which does not grow readily in ordinary culture media each batch of the vaccine shall, in addition to being submitted to the general tests for sterility prescribed in the Rules under the Act, be tested either in a similar manner on media which are specially favourable to the growth of the particular micro-organism from which the vaccine was prepared or by injection into an animal of a species known to be susceptible to infection by the particular organism, and no material from any batch shall be issued unless the batch has passed one of these tests.

(B) Provisions applicable to the production of Vaccine Lymph (Vaccinia Vaccine).

1. *Definition and Proper Name.*—Vaccine Lymph is a preparation of the vaccinal material obtained from the vesicles produced on the skin of healthy animals by inoculation of vaccinia virus. Its proper name is " Vaccine Lymph ".

2. *Staff of Establishment.*—The establishment in which vaccine lymph is prepared must be under the complete direction and control of a competent expert, who must be assisted by a staff adequate for carrying out the operations and tests required during the preparation of the vaccine lymph and in connection with the finished product.

3. *Condition and Housing of Animals.*—(1) The animals used in the production of vaccine lymph must be housed in hygienic conditions in premises satisfactory for this purpose.

(2) Only healthy animals may be used in the production of vaccine lymph. Each animal intended to be used as a source of vaccine lymph must, before being passed for the production of vaccine lymph, be subjected to a period of observation in quarantine for at least seven days. During the period of quarantine the animal must remain free from any sign of disease and must be thoroughly cleaned and groomed.

4. *Precautions to be observed in Preparation.*—(1) A special room, with impervious walls and floor, which can be washed and, when necessary, chemically

disinfected, must be provided for the inoculation of the animals and the collection of the vaccinal material.

(2) The inoculation shall be made on such parts of the animal as are not liable to be soiled by the passage of faeces. The surface used for inoculation shall be shaved and so cleaned as to procure the nearest possible approach to asepsis. Prior to the collection of vaccinal material the inoculated area of the skin shall be cleaned in a similar fashion.

(3) (*a*) Immediately before the vaccinal material is collected, the animal shall be killed. Subsequently a thorough post-mortem examination of the carcase shall be made by a qualified expert. A complete record of each such examination shall be kept, and shall be open to inspection by or on behalf of the licensing authority at any time. If the examination reveals any condition which indicates or suggests that the animal was suffering from any communicable disease (other than vaccinia) the lymph obtained from that animal shall not be issued ; or

(*b*) When post-mortem examination is not carried out each animal shall be kept under observation for a period of at least forty-eight hours after collection of lymph. If during this period the examination reveals any conditions which indicate or suggest that the animal is suffering from any infection other than vaccinia the lymph obtained from that animal shall not be issued.

(4) All instruments and appliances used in the production of vaccine lymph shall be previously subjected to an effective process of sterilisation.

(5) Laboratories in which vaccinal material, after removal from the animal is being manufactured into lymph must be housed in a building separated from stables or animal houses by a reasonable distance. Such laboratories must have impervious walls and floors and must be capable of being readily disinfected when necessary.

(6) All processes concerned with the manufacture of vaccine lymph must be carried out with thorough aseptic precautions.

(7) All vaccinal material must be subjected after collection, to such treatment with glycerol or other partial disinfectants as will bring the content of bacteria and other extraneous micro-organisms of the lymph within the limit prescribed in paragraph 7 of this part of this Schedule.

(8) When the procedures necessary to bring the content of bacteria and other extraneous micro-organisms within the prescribed limit have been completed the vaccine lymph shall be kept continuously in cold storage, at a temperature below 0°C., until it is withdrawn to be filled into containers for issue after which process the filled containers shall immediately be returned to cold storage and kept continuously at a temperature below 0 °C., until required for issue : Provided that it shall be permissible to remove vaccine lymph from one such cold store to another, if adequate precautions are taken during such removal to guard against deterioration.

5. *Containers.*—Vaccine lymph for issue shall be introduced either

(*a*) into previously sterilised capillary glass tubes by a method excluding access of bacteria. The tubes shall then be hermetically sealed at each end. Each tube shall contain a quantity of vaccine lymph suitable for the effective vaccination of one human subject, or

(*b*) into tubes or containers of large dimensions which have been sterilised before the introduction of the lymph and sealed so as to preclude the access of bacteria.

6. *Labelling.*—(1) The label on the container or a label or wrapper affixed to the package to which the container is issued for sale shall bear a statement that the potency of the vaccine lymph cannot be assured for more than seven days from the date of completion of manufacture, unless the lymph is kept continuously at a temperature below 10°C. when the potency can be assured for fourteen days: Provided that it shall be permissible to state that if the lymph is kept continuously below 0°C. the potency can be assured for at least six months.

(2) For the purpose of Rule 109 (3) (*b*) the date on which the manufacture of the batch is completed shall be the date on which the vaccine lymph is removed for issue from cold storage after having been kept continuously at a temperature below 0°C. since the date of filling into containers for issue.

7. *Tests for purity.*—(1) The vaccinal material shall be exposed to the action of glycerol or other partial disinfectant under suitable conditions of temperature until tests made by means of plate cultures have shown that the total number of living bacteria or other extraneous micro-organisms has been reduced to not more than 20 in 1 milligram, or 20,000 in 1 c. c. of the vaccine lymph. The results of these tests shall be recorded and the records kept for inspection. The determination of the content of the living micro-organisms in the vaccine lymph shall be made in a manner approved by the licensing authority and the enumeration of colonies shall be made after incubation for two days at approximately 37°C., and then for at least three days at approximately 20°C.

(2) If *B. anthracis* is found to be present the batch of lymph shall be rejected forthwith, and if *B. Voli* or any other pathogen is found which may prove harmful if introduced into the body by the process of vaccination the lymph must be kept in cold storage till an examination of at least 10 milligrams of 0·01 c.c. of the lymph fails to reveal its presence.

(3) When the prescribed reduction in the number of living micro-organisms has been effected, the batch of vaccine lymph may be issued if—

(*a*) tests carried out in a manner approved by the licensing authority on a sample of not less than 0·1 per cent. of the batch have failed to reveal the presence of *Cl. tetani*; and

(*b*) tests carried out after the process of purification has been completed on a sample of not less than 10 milligrams or 0·01 c.c. have failed to reveal the presence of beta haemolytic streptococci.

8. *Tests for potency.*—(1) Each batch of vaccine lymph, after the process of purification has been completed, shall be tested for potency so as to ensure its activity at the time of issue. These tests shall be applied not more than three months before the batch of lymph is finally issued.

(2) For the purpose of a test for potency a dilution shall be prepared by mixing 1 volume of the lymph with 1,000 volumes of physiological saline solution, or other suitable diluent. The dilution shall be used for the test without filtration.

(3) This dilution of the vaccine lymph shall be tested by application to the suitably prepared skin of a rabbit and the batch of vaccine lymph from which the dilution was prepared shall not be issued unless the lesions characteristic of vaccinia are produced in a susceptible animal. For the purpose of comparison a similar dilution of a lymph of known potency shall be applied simultaneously to the skin of the same animal: Provided that the licensing authority may approve any other form of comparative test for potency which may be submitted to the licensing authority for approval.

(C) PROVISIONS APPLICABLE TO THE PRODUCTION OF VACCINES CONTAINING LIVING ORGANISMS, VIRUSES, OR OTHER POTENTIALLY INFECTIVE AGENTS, OTHER THAN VACCINE LYMPH (VACCINIA).

1. Every substance other than Vaccine Lymph (Vaccinia) containing, or alleged to contain, becteria or virus or other potentially infective agent in the living condition shall be tested in such manner as the licensing authority shall approve in each particular case for the purpose of determining—

(*a*) that the substance contains in living condition the bacteria, virus, or other potentially infective agent, which it is alleged to contain;

(*b*) that its administration is free from danger;

(*c*) that it is free from living organisms other than those which it is alleged to contain.

2 The proper name of such a substance shall be that which the licensing authority, in each particular case, shall approve in writing.

(D) PROVISIONS APPLICABLE TO THE PRODUCTION OF CARBOLISED ANTI-RABIC VACCINE.

1. *Definition and proper name.*—Carbolised anti-rabic vaccine is a sterile suspension of the brain substance of rabbits or sheep or other suitable animals which have died, or been killed when moribund by the administration of an anæsthetic, or other suitable method, after showing characteristic symptoms following subdural inoculation of rabies fixed virus in the form of a suspension of brain substance of rabbits in which the fixed virus strain has been maintained. The virus in the brain suspension shall have been inactivated by the addition of phenol. Its proper name is "Carbolised anti-rabic vaccine".

2. *Strain of fixed Rabies Virus to be used.*—The strain of fixed Rabies Virus to be used in the preparation shall be one approved by the Licensing Authority.

3. *Staff of Establishment.*—The establishment in which carbolised anti-rabic vaccine is prepared must be under the complete direction and control of a competent expert who must be assisted by a staff adequate for carrying out the tests required during the preparation of the vaccine and in connection with the finished product.

4. *Condition and Housing of Animals.*—(1) The animals used in the production of carbolised anti-rabic vaccine must be adequately and healthily housed.

(2) Only healthy animals may be used in the production of carbolised anti-rabic vaccine. Each animal intended to be used as the source of carbolised anti-rabic vaccine must, before being passed for the production of carbolised anti-rabic vaccine, be subjected to a period of observation in quarantine for at least five days. During the period of quarantine the animal must remain free from any sign of disease.

5. *Precautions to be observed in preparation.*—(1) A special room, with impervious walls and floor, which can be washed and, when necessary, chemically disinfected must be provided for the inoculation of animals and the removal

of brains used in the maintenance of the Fixed Virus Strain and the manufacture of carbolised anti-rabic vaccine.

(2) The inoculation of animals and the removal of their brains must be carried out with full aseptic precautions.

(3) Tests for bacterial sterility of brains of animals used for the maintenance of the Fixed Virus Strain for the preparation of carbolised anti-rabic vaccine must be carried out at the time of their removal and any brain material found to show bacterial contamination must not be employed in the manufacture of the vaccine. The sterility tests to be employed shall be those laid down in Rules 114 to 119.

6. *Records.*—The licensee shall maintain permanent records of the origin properties, and characteristics of the Fixed Rabies Virus Strain and of the serial passages made for its maintenance. Records shall be maintained of each animal passage made for the manufacture of the carbolised anti-rabic vaccine and of the manipulation of the brain material used.

7. *Labelling.*—The label on the container shall indicate the percentage of brain substance present in the vaccine.

8. *Issue.*—Carbolised Anti-rabic Vaccine shall not be issued earlier than 10 days from the date of addition of phenol to the brain suspension. A test for presence of phenol must be made before issue.

(E). PROVISIONS APPLICABLE TO TETANUS TOXOID.

1. *Definition and proper name.*—Tetanus Toxoid is tetanus toxin (the sterile filtrate from a culture on nutrient broth of *Clostrudium Tetani*) the specific toxicity of which has been completely removed by the action of chemical substances in such a manner that it retains efficient properties as an immunising antigen. Its proper name is " Tetanus Toxoid ".

2. *Labelling.*—The label on the container shall indicate the dose, or doses, appropriate for administration at one injection to a human subject.

3. *Tests.*—Tetanus Toxoid shall be submitted to the following tests, and it shall not be issued unless it passes *all* of the tests—

(*a*) *Tests for sterility.*—Tetanus Toxoid shall be submitted to the tests for sterility as required under Part X of the Rules, and in addition, it shall be tested on media and under conditions approved by the licensing authority as being specially favourable for the growth of *Clostridium Tetani*;

(*b*) *Tests to determine that the specific toxicity of the toxin used in its preparation has been completely removed.*—5 c.c. of the tetanus toxoid shall be injected into each of not less than five normal guinea-pigs, each weighing from 250 to 350 grammes. If this injection produces any symptom of tetanus in any of the animals injected within 21 days of injection the tetanus toxoid shall be held not to have passed the test.

(*c*) *Tests for potency as an immunising antigen.*—The tests shall be carried out on not less than nine normal guinea-pigs, each weighing from 250 to 350 grammes. Each guinea-pig shall receive by injection the tetanus toxoid, either in a dose of 5 c.c. on one occasion, or in two doses each of 0·1 c.c. on each of two occasions

separated by an interval of ot more than four weeks. It shall be permissible to include in the test guinea-pigs injected by either of these two methods provided that the total number so included is not less than nine. At a date not later than six weeks after the single injection hereinbefore prescribed, or if they have received the two injections, hereinbefore prescribed, at a date not later than two weeks after the second injection, the tetanus antitoxin present in the serum of each guinea-pig shall be determined.

If the serum of each of two-thirds or more of the guinea-pigs tested contains 0·1 international unit or more of tetanus antitoxin per c.c. of serum, or alternatively, if the serum of each of one-third or more of the guinea-pigs tested contains 1 international unit or more of tetanus antitoxin per c.c. of serum, the tetanus toxoid shall be accepted as sufficiently potent.

PROVISIONS APPLICABLE TO TETANUS TOXOID PREPARED FOR ISSUE IN FORMS OTHER THAN SIMPLE SOLUTION.

4. *Proper name.*—The proper name of any form of tetanus toxoid other than that of simple solution shall be "Tetanus Toxoid" together with a phrase indicating the nature of the additional process to which it has been subjected, *e.g.*, "Tetanus Toxoid, Alum Precipitated", or "Alum precipitated Tetanus Toxoid".

5. *Labelling.*—The label on the container shall indicate the dose, or doses, appropriate for administration at one injection to a human subject.

6. *Tests.*—(*a*) When tetanus toxoid is prepared for administration in forms other than simple solution, such as Alum precipitated Tetanus Toxoid, the tetanus toxoid from which such forms are prepared shall be submitted to, and shall pass, the tests for sterility and for absence of specific toxicity hereinbefore prescribed.

(*b*) The product, after precipitation or other process used for its final preparation, shall again, subjected to the sterility tests hereinbefore prescribed with such modifications as the nature of the product may require to make the test effective.

(*c*) The product, after the precipitation or other process used for its final preparation, shall be subjected to the tests for absence of specific toxicity and for potency as an immunising antigen hereinbefore prescribed, with the modification that the dose injected in the test for absence of specific toxicity and in the test for potency as an immunising antigen when a single dose is administered shall be 1 c.c.

PART II.—TOXINS AND ANTIGENS.

(A) PROVISIONS APPLICABLE TO THE REAGENTS USED IN THE SCHICK TEST FOR THE DIAGNOSIS OF SUSCEPTIBILITY TO DIPHTHERIA.

1. *Definition and proper names.*—(1) The reagents used in the Schick test are two, Schick Toxin and Schick Control. Their proper names respectively are "Schick Test Toxin" and "Schick Control".

(2) Schick Test Toxin is a sterile filterate from a culture on nutrient broth of the specific organism of Diphtheria (*Corynebacterium diphtheria*). It may be issued either—

(*a*) undiluted, accompanied by a container in the same box or carton holding such a volume of sterile saline solution as, when mixed with the accompanying quantity of the undiluted toxin, will make a dilution of the strength proper for use in the test. The proper name of the substance in this form is "Schick Test Toxin (undiluted)"; or

(*b*) already diluted with an appropriate saline solution to the strength proper for use in the test. The proper name of the substance in this form is "Schick Test Toxin (diluted for use)".

(3) Schick Control is prepared from the same batch of Schick Toxin as that with which it is used for sale, by destroying the specific toxicity. This is effected by heating the toxin in such a manner as to keep it at a temperature not lower than 70 C. for a time not shorter than five minutes. Schick Control is issued in a dilution not weaker than that in which the corresponding toxin is used in the test.

(4) The dilution of Schick Toxin proper for the test is that in which 0·2 c.c. contains one test dose.

2. *Tests for potency.*—The test dose of Schick Toxin for the purpose of the foregoing provision shall be measured by the following tests:—

(*a*) by intracutaneous injection into normal guinea-pigs in mixtures with different proportion of diphtheria antitoxin. One test dose mixed with 1/750th or more of a unit of antitoxin must cause no local reaction, but mixed with 1/1250th or less of a unit of antitoxin must cause a definite local reaction of the type known as the "positive Schick reaction";

(*b*) by intracutaneous injection into normal guinea-pigs, without admixture with anti-toxin. 1/50th of one test dose must not cause, and 1/25th of one test dose must cause, a definite local reaction of the type known as the "positive Schick reaction".

3. *Application of Rule 120.*—Rule 120 shall apply to Schick Toxin (diluted for use) as being a substance so unstable in solution that the delay occasioned by the completion of the sterility test on filled containers prescribed by the Rules would render its issue in active form impossible.

(B) PROVISIONS APPLICABLE TO DIPHTHERIA PROPHYLACTIC.

1. *Definition and proper name.*—Diphtheria Prophylactic is diphtheria toxin (the sterile filtrate from a culture on nutrient broth of *Corynebacterium diphtheria*), or material derived therefrom the specific toxicity of which has been reduced to a low value either by the action of chemical substances, or by the addition of diphtheria antitoxin, or by both methods, but, in any case, in such a manner that it retains efficient properties as an immunising antigen. Its proper name is "Diphtheria Prophylactic".

2. *Labelling.*—The label on the container shall bear a statement of the dose (hereinafter referred to as the "human dose") appropriate for administration at one injection to a human subject.

3. *Tests.*—Diphtheria Prophylactic shall be submitted to the following tests :—

(*a*) *Tests to determine that the specific toxicity of the toxin used in its preparation has been so reduced that it does not exceed the prescribed maximum.*—Five human doses of the Diphtheria Prophylactic under test shall be injected into each of five normal guinea-pigs each weighing 250 to 350 grammes. This injection must not cause the death of any of the guinea-pigs within six days following the injection. If all the guinea-pigs injected survive for six days but any of them die within thirty days following the injection from the specific toxaemia, one human dose of the Diphtheria Prophylactic under test shall be injected into each of five normal guinea-pigs, each weighing 250 to 350 grammes. This injection must not cause the death of any of the guinea-pigs within 30 days following the injection.

If a batch of Diphtheria Prophylactic is shown by either of these tests to have a greater toxicity than the maximum hereby indicated, it shall not be issued unless and until the toxicity has been so reduced by further treatment that it does not exceed that maximum.

(*b*) *Tests for potency as an immunizing antigen.*—A quantity of Diphtheria Prophylactic not exceeding five human doses shall be injected on one occasion into each of at least ten normal guinea-pigs; or, alternatively, a quantity of Diphtheria Prophylactic not exceeding one-tenth of a human dose shall be injected into each of at least ten normal guinea-pigs on each of two occasions, separated by an interval of not more than four weeks. The guinea-pigs shall be tested for immunity to diphtheria toxin, if they have received the single injection hereinbefore prescribed, at a date not later than six weeks after injection, and if they have received the two injections hereinbefore prescribed, at a date not later than three weeks after the second injection, by intracutaneous injection into each guinea-pig of one test dose of Schick Toxin. If more than two out of ten guinea-pigs thus tested or more than one quarter of the number tested if this is greater than ten exhibit a positive Schick reaction, the batch of Diphtheria Prophylactic shall be treated as insufficiently potent, and shall not be issued :

Provided that in the case of the forms of Diphtheria Prophylactic known as Toxin-Antitoxin Floccules and Toxoid-Antitoxin Floccules the Prophylactic may be similarly injected into nine or more normal guinea-pigs which may be tested for immunity to Diphtheria Toxin by two separate but simultaneous intracutaneous injections into each of at least nine of these guinea-pigs of one test dose and two test doses, respectively, of Schick Toxin. If two-thirds or more of the guinea-pigs tested do not exhibit a positive-reaction to *one* test dose of Schick Toxin; or alternatively, if one-third or more of the guinea-pigs tested do not exhibit a positive reaction to *two* test doses of Schick Toxin, the batch shall be accepted as sufficiently potent.

(C) PROVISIONS APPLICABLE TO TUBERCULINS AND OTHER PREPARATIONS FROM THE BACILLUS TUBERCULOSIS AND ITS CULTURES.

(NOTE.—The name "tuberculin" has been frequently applied to any extract, suspension or other preparation of the *Bacillus tuberculosis* or of media on which that bacillus has been cultivated. In the following Part of this Schedule the name is used in a more restricted sense and applies only to tuberculins as therein defined.)

TUBERCULINS.

1. *Definition and proper name.*—(1) Tuberculins are preparations of fluid media on which the *Bacillus tuberculosis* has been grown in artificial culture and which have been freed by filteration from the bacilli.

(2) For the purposes of this Schedule tuberculins are classified in two groups (*a*) Old Tuberculin, and (*b*) Tuberculin Bouillon Filtrate.

2. *Old Tuberculin.*—(1) Old Tuberculin is the concentrated filtrate from the growth of *Bacillus tuberculosis* on a suitable nutrient broth. For its preparation the bacillus must be grown at approximately 37°C, for a period, usually not less than 6 weeks, sufficient to allow the surface of the fluid medium to become covered by a thick growth of the bacillus. At the end of this period the fluid medium, from which the bacilli may or not have been previously separated by filtration, must be concentrated by evaporation to one-tenth its original volume, and then be filtered. If the repuired test for potency shows that the preparation so concentrated is more potent than the standard preparation, the potency may be reduced to the required degree by appropriate dilution. If the test shows that the potency is less than that of the standard preparation, it shall not be increased by further evaporation. The proper name of the preparation is "Old Tuberculin" with or without a suffix such as T., or P.T. The suffix T., if used, will indicate that the bacillus used in preparing the Tuberculin was obtained from a case of human infection, and the suffix P. T. that the bacillus used was obtained from a case of bovine infection.

(2) The standard preparation of Old Tuberculin, is a quantity of Old Tuberculin kept in the National Institute for Medical Research, Hampstead.

(3) Each batch of Old Tuberculin shall be tested for potency by observation of its specific toxicity, by a method approved by the licensing authority, in such a way that the potency of the preparation under test is measured by comparison with that of the standard preparation. Old Tuberculin shall not be issued if its activity differs from that of the standard preparation to such an extent that the difference is revealed by the test.

(4) Each batch of Old Tuberculin shall be tested for the absence of non-specific toxicity by the subcutaneous injection of 0·5 c.c. into a normal guinea—pig, and shall be treated as having passed the test if such injection does not cause death or serious symptoms.

3. *Tuberculin Bouillus filtrate.*—(1) Tuberculin Bouillon Filtrate is the unconcentrated Filtrate from the growth of Bacillus tuberculosis on a suitable nutrient broth. For its preparation the bacillus must be grown at approximately 37°C, for a period usually not less than 6 weeks, sufficient to allow the surface of the fluid medium to become covered by thick growth of the bacillus. At the end of this period the medium is freed from bacill by filtration through a bacteria-proof filter. The proper name of the preparation is "Tuberculin Bouillon Filtrate," with or without a suffix such as T. O. A. or P. T. O. The suffix T. A. O., if used, will indicate that the bacillus used in preparing the Tuberculin Bouillon Filtrate was obtained from a case of human infection: and the suffix P. T. O. will indicate that the bacillus used was obtained from a case of bovine infection.

(2) Each batch of Tuberculin Bouillon Filtrate shall be tested for the absence of non-specific toxicity by the subcutaneous injection of 5 c.c. into a normal

guinea-pig, and shall be treated as having passed the test if such injection does not cause death or serious symptoms.

4. *Test for sterility.*—All tuberculins shall be tested for sterility in accordance with Rules 115 to 119. Tuberculin Bouillon Filtrate shall be tested in addition for absence of living tubercle bacilli by a method satisfactory to the licensing authority.

TUBERCLE VACCINES.

5. *Definition and proper name.*—Tubercle vaccines are preparations made from the bacillary substance obtained by growth of the Bacillus tuberculosis on artificial media, and consisting of suspensions of the killed organisms or of products therefrom, in water or other suitable suspending fluids. The proper name is "Tubercle Vaccine", and any other descriptive title or symbol indicating the origin of the bacilli or the nature of the process of preparation must be used in addition to, and not in substitution for the name " Tubercle Vaccine".

6. *Application of provisions as to bacterial vaccines.*–The provisions of Part I (A) of this Schedule (which relates to the production of bacterial vaccines) shall apply to the production of tubercle vaccines.

(D) PROVISIONS APPLICABLE TO STAPHYLOCOCCUS TOXOID.

1. *Definition and proper name.*–Staphylococcus Toxoid is staphylococcus toxin (the sterile filtrate from a culture on a suitable medium of a toxigenic strain of staphylococcus), the specific toxicity of which has been reduced to a low value by the action of chemical substances in such a manner that it retains efficient properties as an immunising antigen. Its proper name is " Staphylococcus Toxoid ".

Staphylococcus Toxoid may be issued either—

(*a*) undiluted ; or

(*b*) already diluted with an appropriate saline solution to the strength suitable for injection.

2. *Labelling.*—The label on the container shall indicate the dose, or doses, appropriate for administration at one injection to a human subject.

3. *Tests.*—Staphylococcus Toxoid shall be submitted to the following tests, it shall not be issued unless it passes all of the tests :—

(*a*) *Tests to determine that the specific toxicity of the toxin used in its preparation has been sufficiently reduced*—

(*i*) One volume of the undiluted staphylococcus toxoid shall be added to four volumes of physiological saline solution; equal volumes of this dilution staphylococcus toxoid and of a 2 per cent. suspension of washed red blood corpuscles of the rabbit shall be mixed; when the mixture is heated to 37°C. for one hour, there must be no significant hæmolysis.

(*ii*) 0·2 c.c. of the undiluted staphylococcus toxoid shall be injected intracutaneously into a normal rabbit or guinea-pig; this injection may cause a slight local reaction, but must not produce necrosis.

(*iii*) Two rabbits shall be injected intravenously with doses of staphylococcus toxoid calculated at the rate of 2·5 c.c. per kilogram body weight; this injection must not cause the death of either rabbit within three days following the injection.

(*b*) *Test of non-specific toxicity.*—Two normal mice shall be injected intraperitoneally with 0·5 c.c. of the undiluted toxoid; this injection must not cause the death of either animal within seven days following the injection.

(*c*) *Tests for potency as an immunising antigen.*—1 c.c. of the undiluted staphylococcus toxoid shall be injected into each of not less than nine normal guinea-pigs on each of two occasions separated by an interval of not more than four weeks; at a date not later than two weeks after the second injection the staphylococcus antitoxin present in the serum of each guinea-pig shall be determined.

If the serum of each of two-thirds or more of the guinea-pigs tested contains 0·5 unit or more of staphylococcus antitoxin per c.c. of serum, or alternatively if the serum of each of one-third or more of the guinea-pigs tested contains 1 unit or more of staphylococcus antitoxin per c.c. of serum, the toxoid shall be accepted as sufficiently potent.

PART III.—PROVISIONS APPLICABLE TO THE PRODUCTION OF ALL SERA FROM LIVING ANIMALS.

1. *Condition and housing of animals.*—(1) The animals used in the production of sera must be adequately and healthily housed.

(2) Only healthy animals may be used in the preparation of sera, and in particular the presence of glanders in horses or other equidae and of tuberculosis in cattle must be excluded by testing with mallein and tuberculin respectively.

(3) Every new animal intended to be used as a source of serum must be subjected to a period of observation in quarantine for at least 7 days, before being admitted to the stables in which the serum-yielding animals are housed.

(4) Every animal used as a source of serum must either be actively immunized against tetanus toxin or must be passively immunized against that toxin by injections of tetanus antitoxin in such doses as to ensure the constant presence of that antitoxin in the blood during the whole period of the use of the animal as a source of serum.

2. *Staff of Establishment.*—The establishment must be under the complete direction and control of a competent expert in bacteriology and serology, assisted by a staff adequate for carrying out the tests required during the preparation of the sera and in connection with the finished products.

3. *Precautions to be observed in preparation.*—(1) Laboratories where sera are exposed to the air in the course of the process of preparation must be separated by a sufficient distance from stables and animal houses to avoid the risk of aerial contamination with bacteria from animal excreta, and must be rendered fly-proof to prevent such contamination by insects. Such laboratories must have impervious walls and floors and must be capable of being readily disinfected when necessary.

(2) A special room with impervious walls and floor which can be washed and, when necessary, chemically disinfected must be provided for the collection of blood from the living animal.

(3) An efficient system of manure removal must be used, which will prevent its accumulation in the vicinity of any room where blood or serum is collected or handled.

(4) An adequate number of efficient sterilizers must be provided for the sterilization of all glassware or other apparatus with which the serum may come into contact in the course of its preparation.

(5) All processes to which the serum is subjected during and after its collection from the animal, must be designed to preserve its sterility, but in the case of artificially concentrated sera, it shall suffice that the process of concentration is conducted with scrupulous cleanliness and in such a manner as to avoid unnecessary or dangerous contamination.

(6) The laboratories in which the testing of the sera for potency, sterility and freedom from abnormal toxicity are carried out must be adequate for the purpose. An adequate supply of animals for use in such tests and suitable housing for such animals must be provided.

(7) Provision must be made for complying with any special conditions which may be laid down in this Schedule relating to the production and issue of the particular serum, in respect of which the licence is granted.

4. *Unhealthy or infected animals.*—If an animal used in the production of sera is found to be suffering from an infection, except one produced by living organisms against which it is being immunized, or shows signs of serious or persistent ill-health not reasonably attributable to the process of immunization, the licensee shall immediately report the matter to the licensing authority and shall, if the authority orders an inspection and the inspector so directs, cause such animal to be killed and a *post-mortem* examination of it to be made, and take steps to prevent any serum obtained from the animal being sold or offered for sale until permission is given by the authority. If the result of the *post-mortem* examination is such as to bring under suspicion the health of any of the other animals used for the production of sera, the licensing authority may prohibit the use of those animals for the production of sera or may take such other steps as may be necessary to prevent the issue of sera, which may be dangerous to human health :

Provided that in a case of emergency the person in charge of the establishment may order the destruction of an animal used in the production of sera and suspected of infection, and shall in that case give notice forthwith to the licensing authority and shall permit an inspector to be present at the *post-mortem* examination.

PART IV.—PROVISIONS APPLICABLE TO PARTICULAR SERA AND ANTITOXINS.

(A) PROVISIONS APPLICABLE TO ANTI-BACTERIAL SERA AND ANTITOXIC SERA FOR WHICH NO POTENCY TEST IS PRESCRIBED.

NOTE.—The sera and antitoxins to which this Part of this Schedule applies are the sera or solutions of the purified proteins of sera separated from the blood of animals which have been artificially immunised against cultures of one or more organisms or against a soluable toxin or toxins produced by the organism or organisms or against antigenic substances prepared from the organism or organisms.

1. *Proper Name.*—The proper name of any anti-bacterial serum to which Division A of this Part of this Schedule applies shall be the recognised scientific name of the organism or some generally recognised abbreviation thereof, preceded

by the prefix " anti ", and followed by the word " serum ", as, for example, " anti-meningoeoecus serum ". The proper name of any antitoxie serum may be formed from the word " antitoxin ", preceded by the name of the organism from which the toxin was prepared, and followed, if desired, by a term indicating the source or the strain of that organism, for example, " streptococcus antitoxin (Scarlatina) ".

2. *Quality.*—(1) Any such serum, shall be issued for therapeutic use in the form of either—

(*a*) natural serum, *i.e.*, the liquid product of decantation of the coagulated blood or plasma without any addition, other than antiseptic, or subtraction: or

(*b*) a solution of the purified serum proteins containing the specific antibodies.

(2) At the time of issue, the liquid shall be clear or show, at most, a slight opalescence or precipitate. Preparations of the natural serum shall not contain more than 10 per cent. of solid matter. A solution of the serum protein shall not contain more than 20 per cent. of solid matter.

3. *Labelling.*—(1) The label on the container shall indicate the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, or a solution of the purified serum proteins.

4. *Cultures.*—The cultures used in immunizing the animals shall be at all times open to inspection, and specimens shall be furnished for examination at the request of the licensing authority.

5. *Records.*—(1) The permanent records which the licensee is required to keep shall include the following particulars—

(*a*) as to the cultures—

(*i*) the source from which the culture was obtained;

(*ii*) the nature of the material from which the culture was isolated and the date of its isolation; and

(*iii*) evidence of the identity and specificity of the culture;

(*b*) as to the procedure used in immunizing the animals—

(*i*) the method of preparing the culture or antigen used for immunization;

(*ii*) the dosage and methods employed in administering the culture or antigen;

(*iii*) the period in the course of immunization at which blood is withdrawn for preparation of the serum.

(*c*) any tests which may have been applied to the serum to determine its content of specific antibodies or its specific therapeutic potency.

(2) If the licensee desires to treat the performance of any test recorded under sub-paragraph (1) (*c*) of this paragraph as determining the date of completion of manufacture for the purposes of Rule 109 he shall submit full particulars of the proposed test to the licensing authority and obtain his approval.

(B) PROVISIONS APPLICABLE TO ANTI-DYSENTERY SERUM (SHIGA) AND OTHER ANTI-DYSENTERY SERA.

ANTI-DISENTERY SERUM (SHIGA).

1. *Proper Name.*—Anti-dysentery serum (Shiga) is the serum or the globulins containing the specific immune substances, separated from the blood of animals which have been immunized against the toxins, cultures or bacterial substances obtained by artificial culture of the *Bacillus dysenteriae* (Shiga). The proper name of the substance is " Anti-dysentery Serum (Shiga) ".

2. *Standard preparation.*—The standard preparation is a quantity of dried serum, obtained from horses immunized against the toxic constituents of the *Bacillus dysenteriae* (*Shiga*), and kept in the National Institute for Medical Research, Hampstead.

3. *Quality.*—(1) Anti-dysentry serum (Shiga) shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood or plasma of the immunized animals; or

(*b*) the solution of the globulins containing the specific immune substances; or

(*c*) a dry powder prepared from (*i*) the natural serum or (*ii*) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation, of the coagulated blood without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent. of total solid matter. A solution of the separated antitoxic globulins shall not contain more than 20 per cent. of total solid matter.

4. *Strength.*—(1) The potency of anti-dysentery serum, with respect to its content of antibodies for the toxic constituents of the *Bacillus dysenteriae* (*Shiga*) shall be determined by intravenous injection into mice of mixtures of the serum with a solution or suspension of the said toxic constituents, which solution or suspension has been standardised in relation to the standard preparaton of anti-dysentery serum.

(2) Each container of anti-dysentery serum (Shiga) shall contain a sufficient number of units in excess of the minimum total number or units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109 (3) (*d*) as the date up to which the preparation may be expected to retain its potency.

5. *Unit of Standardzation.*—The unit of anti-dysentery serum (Shiga) for the purposes of these Rules is the specific neutralising activity for the *Bacillus dysenteriae* (Shiga) contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container; and

(*b*) either (*i*) the potency of the preparation with respect to its antitoxic value for the toxic constituents of the *Bacillus dysenteriae* (*Shiga*), expressed as the minimum number of units per c.c. in the case of liquid products, or as the minimum number of units per gramme in the case of dry products; or (*ii*) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, or a solution of the globulins containing the specific immune substances, or a dried natural serum or dried globulins.

OTHER ANTI-DYSENTERY SERA.

7. *Proper Names.*—Anti-dysentery sera prepared by immunizing animals against bacilli producing dysentery in man, other than the *B. dysenteriae* (*Shiga*), shall conform with the provisions of Division (A) of this Part of this Schedule which are applicable to sera for which no potency test is prescribed. The proper name shall in each case be "Anti-dysentery Serum", followed, in brackets, by the personal name or other symbol by which the particular strain or strains of dysentery bacilli are identified by bacteriologists—as, for example, "Anti-dysentery Serum (Flexner)", "Anti-dysentery Serum (Y)", "Anti-dysentery Serum (Flexner, Y)".

8. *Mixed sera.*—A mixed anti-dysentery serum, prepared by immunizing animals against the *B. dysenteriae* (*Shiga*) and in addition against one or more of the other bacilli associated with human dysentery shall conform with the provisions of Division (A) of this Part of the Schedule, and shall also, with respect to its content of immune substances for the *B. dysenteriae* (*Shiga*) and its products, conform with paragraphs 3, 4, 5 and 6 (2) in Division (B) thereof, and the number of units shown on the label shall indicate the neutralizing value of the serum for the products of the *B. dysenteriae* (*Shiga*) only. The proper name of such a serum shall be "Anti-dysentery Serum" followed, in brackets, by the names of symbols indicating the strains used in its preparation, as, for example, "Anti-dysentery Serum (Shiga, Flexner, Y)".

(C) PROVISIONS APPLICABLE TO DIPHTHERIA ANTITOXIN.

1. *Definition and Proper Names.*—Diphtheria antitoxin is the serum or the antitoxic-globulins separated from the blood of animals which have been immunized against diphtheria toxin. When the serum or antitoxie globulins are obtained from the blood of horses or other equidae, the proper name of the substance is "diphtheria antitoxin". When the serum or antitoxie globulin are obtained from animals other than horses or other equidae, the proper name is "diphtheria antitoxi" followed by the common name of the animal from which the substance is prepared.

2. *Standard preparation.*—The standard preparation is a quantity of dried diphtheria antitoxin kept in the National Institute for Medical Research, Hampstead, London.

3. *Strength.*—(1) Diphtheria antitoxin having a potency of less than 400 units per c.c. in the case of liquid preparations, or less than 4,000 units per gramme in the case of dried preparations shall not be issued.

(2) Each container of diphtheria antitoxin shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109 (3) (*d*) as the date up to which the preparation may be expected to retain its potency.

4. *Quality.*—(1) Diphtheria antitoxin shall be issued for therapeutic and prophylactic use in the form of either—

(*a*) the serum separated from the blood or plasma of animals immunized against diphtheria toxin; or

(*b*) the solution of the globulins containing the specific antitoxin; or

(*c*) a dry powder prepared from (*i*) the natural serum or (*ii*) the antitoxic globulins containing no antiseptic or other added substance.

(2) If issued in fluid form the liquid at the time of issue shall be clear or shall show, at most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent. of solid matter. A solution of the separated antitoxic globulins shall not contain more than 0·1 gramme of solid matter for each 500 antitoxin units.

5. *Unit of standardization.*—The unit of diphtheria antitoxin for the purposes of these Rules is the specific neutralizing activity for diphtheria toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Test for potency.*—The potency in units of diphtheria antitoxin shall be determined in accordance with a method approved by the licensing authority by the injection into guinea-pigs of a mixture consisting of the antitoxin under test and of a diphtheria toxin which has been standardized in relation to the standard preparation.

7. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container; and

(*b*) either (*i*) the potency of the preparation expressed as the minimum number of units of antitoxin per c.c. in the case of liquid products, or as the minimum number of units of antitoxin per gramme in the case of dry products; or (*ii*) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, or a solution of antitoxic globulins, dried natural serum, or dried antitoxic globulins.

(D) PROVISIONS APPLICABLE TO TETANUS ANTITOXIN.

1. *Proper Name.*—Tetanus Antitoxin is the serum, or the antitoxic globulins separated from the blood of animals which have been immunized against tetanus toxin. The proper name of the substance is " Tetanus antitoxin ".

2. *Standard preparation.*—The standard preparation is a quantity of dried tetanus antitoxin kept in the National Institute for Medical Research, Hampstead, London.

3. *Strength.*—(1) Tetanus antitoxin having a potency of less than 300 units per c.c. in the case of liquid preparations, or less than 3,000 units per gramme in the case of dried preparations, shall not be issued for prophylactic use.

Tetanus antitoxin having a potency of less than 1,600 units per c.c. in the case of liquid preparations, or less than 16,000 units per gramme in the case of dried preparations shall not be issued for the treatment of tetanus.

(2) Each container of tetanus antitoxin shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109 (3) (*d*) as the date up to which the preparation may be expected to retain its potency.

4. *Quality.*—(1) Tetanus antitoxin shall be issued for therapeutic and prophylactic use in the form of either—

(*a*) the serum separated from the blood or plasma of animals immunized against tetanus toxin; or

(*b*) the solution of the globulins containing the specific antitoxin; or

(*c*) a dry powder prepared from (*i*) the natural serum or (*ii*) the antitoxic globulins, and containing no antiseptic or other added substance.

(2) If issued in fluid form the liquid at the time of issue shall be clear or show at most a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of deantation of the coagulated blood without any addition, other than antiseptic, or substraction) shall not contain more than 10 per cent. of total solid matter. A solution of the separated antitoxic globulins shall not contain more than 0·1 gramme of solid matter for each 600 antitoxin units.

5. *Unit of standardization.*—The unit of tetanus antitoxin for the purposes of these Rules is the specific neutralizing activity for tetanus toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.*

6. *Test for potency.*—The potency in units of tetanus antitoxin shall be determined by the subcutaneous injection into guinea-pigs or mice of mixtures of the preparation with a tetanus toxin which has been standardised in relation to the standard preparation of tetanus antitoxin. The neutralizing value may be determined by observation either—

(*a*) of the greatest dose which fails to protect a guinea-pig or mouse from death within 4 days, or

(*b*) of the least dose which suffices to protect a mouse or guinea-pig from the appearance of symptoms of tetanus.

* This unit is one-half of the unit established in the United States of America under the authority of an Act of the 1st July 1902.

7. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container; and

(*b*) either (*i*) the potency of the preparation expressed as the minimum number of units of antitoxin per c.c. in the case of liquid products, or as the minimum number of units of antitoxin per gramme in the case of dry products; or (*ii*) the total number of c.c. in the container; and

(*c*) a statement* that the numbers of units indicated are equivalent to one-half of those numbers of American units.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular products, that is to say, whether natural rum, a solution of antitoxic globulins, dried natural serum, or dried antitoxic obulins.

(E) PROVISIONS APPLICABLE TO GAS-GANGRENE ANTITOXIN (PERFRINGENS).

1. *Proper Names.*—Gas-Gangrene Antitoxin (perfringens) is the serum, or the antitoxic globulins separated from the blood of animals which have been immunised against the specific toxin prepared by the growth of *Bacillus perfringens* (*B. welchii*) in a fluid medium. The proper name of the substance, is "Gas-Gangrene Antitoxin (perfringens)."

2. *Standard Preparation.*—The standard preparation is a quantity of dried gas-gangrene antitoxin (perfringens) kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality.*—(1) Gas-gangrene antitoxin shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood or plasma of the immunised animals;

or

(*b*) the solution of the globulins containing the specific immune substances;

or

(*c*) a dry powder prepared from (*i*) the natural serum [or (*ii*) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent. of solid matter. A solution of the separated antitoxic globulins shall not contain more than 20 per cent. of total solid matter.

4. *Strength.*—(1) The potency in units of gas-gangrene antitoxin (perfringens) shall be determined, in accordance with a method approved by the licensing authority, by the injection into animals of a mixture of the antitoxin under test with a gas-gangrene (perfringens) toxin which has been standardised in relation to the standard preparation of gas-gangrene antitoxin (perfringens).

(2) Each container of gas-gangrene antitoxin (perfringens) shall contain a sufficient number of units in excess of the minimum total number of units

* The statement may be conveniently given in arithmetical form, thus for example:—
"2,000 units (=1,000 American units)".

indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109 (3) (*d*) as the date up to which the preparation may be expected to retain its potency.

5. *Unit of Standardization.*—The unit of gas-gangrene antitoxin (perfringens) for the purposes of these Rules is the specific neutralizing activity for gas-gangrene (perfringens) toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container; and

(*b*) either (*i*) the potency of the preparation expressed as the minimum number of units of antitoxin per c.c. in the case of liquid products or as the minimum number of units of antitoxin per gramme in the case of dry products; or (*ii*) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of antitoxic globulins, dried natural serum or dried antitoxic globulins.

7. *Mixed Antitoxins.*—A mixed antitoxin, containing antitoxins against other toxins than that of the *Bacillus perfringens*, shall with respect to its content in units of gas-gangrene antitoxin (perfringens), conform with paragraphs 4, 5 and 6.

(F) Provisions applicable to Gas-gangrene Antitoxin (Oedematiens.)

1. *Proper Name.*—Gas-Gangrene Antitoxin (oedematiens) is the serum, or the antitoxic globulins, separated from the blood of animals which have been immunised against the specific toxin prepared by the growth of *clostridium oedematiens* in a fluid medium. The proper name of the substance is "Gangrene Antitoxin (oedematiens)".

2. *Standard Preparation.*—The standard preparation is a quantity of dried gas-gangrene antitoxin (oedematiens) kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality.*—(1) Gas-Gangrene Antitoxin (oedematiens) shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood or plasma of the immunised animals; or

(*b*) the solution of the globulins containing the specific inmune substances; or

(*c*) the dried solid prepared from (*i*) the natural serum or (*ii*) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show at most, a very slight opalescence or precipitate. Preparations of the natural serum

(the liquid product of decantation of the coagulated blood or plasma without any addition other than antiseptic, or substraction) shall not contain more than 10 per cent of solid matter. A solution of the separated antitoxic globulins shall not contain more than 20 per cent of solid matter.

4. *Strength.*—(1) The potency in units of gas-gangrene antitoxin (oedematiens) shall be determined by a method approved by the licensing authority, by the injection into animals of a mixture of the antitoxin under test which a gas-gangrene (oedematiens) toxin which has been standardised in relation to the standard preparation of gas-gangrene antitoxin (oedematiens).

(2) Each container of gas-gangrene antitoxin (oedematiens) shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109 (3)(*d*) the date up to which the preparation may be expected to retain its potency.

5. *Unit of Standardisation.*—The unit of gas-gangrene antitoxin (oedematiens) for the purposes of these Rules is the specific neutralising activity for gas-gangrene (oedematiens) toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container ; and

(*b*) either (*i*) the potency of the preparation expressed as the minimum number of units of antitoxin per c.c. in the case of liquid products, or as the minimum number of units of antitoxin per gramme in the case of dry products : or (*ii*) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product , that is to say, whether natural serum a solution of antitoxic globulins, dried natural serum or dried antitoxic globulins.

7. *Mixed Antitoxins.*—A mixed antitoxin, containing antitoxins against other toxins than that of *clostridium oedematiens* shall, with respect to its content in units of gas-gangrene antitoxin (oedematiens) conform with paragraphas 4, 5 and 6.

(G) Provisions applicable to Gas-gangrene Antitoxin (Vibrion Septique.)

1. *Proper Name.*—Gas -Gangrene Antitoxin (vibrions septique) is the serum or the antitoxic globulins, separated from the blood of animals which have been immunised against the specific toxin prepared by the growth of the *clostridium* commonly known as vibrion septique in a fluid medium. The proper name of the substance is "Gas-Gangrene Antitoxin (vibrion septique)".

2. *Standard Preparation.*—The standard preparation is a quantity of dried gas-gangrene antitoxin (vibrion septique) kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality.*—(1) Gas-Gangrene Antitoxin (vibrion septique) shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood of plasma of the immunised animals ; or

(*b*) the solution of the globulins containing the specific immune substances ; or

(*c*) the dried solid prepared from (*i*) the natural serum or (*ii*) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at most , a very slight opaloscence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood or plasma without any addition other than antiseptic, or subtraction) shall not contain more than 10 per cent. of solid matter. A solution of the separated antitoxic globulins shall not contain more than 20 per cent of solid matter.

4. *Strength.*—(1) The potency in units of gas-gangrene antitoxin (vibrion septique) shall be determined, by a method approved by the licensing authority, by the injection into animals of a mixture of the antitoxin under test with a gas-gangrene (vibrion septique) toxin which has been standardised in relation to the standard preparation of gas-gangrene antitoxin (vibrion septique).

(2) Each container of gas-gangrene antitoxin (vibrion septique), shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109 (3) (*d*) as the date up to which the preparation may be expected to retain its potency.

5. *Unit of Standardisation.*—The unit of gas-gangrene antitoxin (vibrion septique) for the purposes of these Rules is the specific neutralising activity for gas-gangrene (vibrion septique) toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit, accepted for international use.

6. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container ; and

(*b*) either (*i*) the potency of the preparation expressed as the minimum number of units of antitoxin per c.c. in the case of liquid products or as the minimum number of units of antitoxin per gramme in the case of dry products ; or (*ii*) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of antitoxic globulins, dried natural serum or dried antitoxic globulins.

7. *Mixed Antitoxins.*—A mixed antitoxin, containing antitoxins against other toxins than that of the *clostridum* commonly known as vibrion septique shall, with respect to its content in units of gas-gangrene antitoxin (vibrion septique) conform with paragraphs 4, 5 and 6.

(H) PROVISIONS APPLICABLE TO GAS-GANGRENE ANTITOXIN (HISTOLYTICUS.)

1. *Proper Name.*—Gas-Gangrene Antitoxin (histolyticus) is the serum, or the antitoxic globulins, separated from the blood of animals which have been immunised against the specific toxin prepared by the growth of *clostridium histolyticus* in a fluid medium. The proper name of the substance is " Gas-Gangrene Antitoxin (histolyticus) ".

2. *Standard Preparation.*—The standard preparation is a quantity of dried gas-gangrene antitoxin (histolyticus) kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality.*—(1) Gas-Gangrene Antitoxin (histolyticus) shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood plasma of the immunised animals ; or

(*b*) the solution of the globulins containing the specific immune substances ; or

(*c*) the dried solid prepared from (*i*) the natural serum or (*ii*) the globulin containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at most, a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood or plasma without any addition other than antiseptic, or substraction) shall not contain more than 10 per cent. of solid matter. A solution of the separated antitoxic globulins shall not contain more than 20 per cent. of solid matter.

4. *Strength.*—(1) The potency in units of gas-gangrene antitoxin (histolyticus) shall be determined, in accordance with a method approved by the licensing authority by the injection into animals, of a mixture of the antitoxin under test with a gas-gangrene (histolyticus) toxin which has been standardised in relation to the standard preparation of gas-gangrene antitoxin (histolyticus).

(2) Each container of gas-gangrene antitoxin (histolyticus) shall contain a sufficient number of units in excess of the minimum total number of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109(3)(*d*) of these Rules as the date up to which the preparation may be expected to retain its potency.

5. *Units of Standardisation.*—The unit of gas-gangrene antitoxin (histolyticus) for the purposes of these Rules is the specific neutralising activity for gas-gangrene (histolyticus) toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container ; and

(*b*) either (*i*) the potency of the preparation expressed as the minimum number of units of antitoxin per c.c. in the case of liquid products, or as the minimum number of units of antitoxin per gramme in the case of dry products ; or (*ii*) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum a solution of antitoxin globulins, dried natural serum or dried antitoxin globulins.

7. *Mixed Antitoxins.*—A mixed antitoxin containing antitoxins against other toxins than that of *clostridium histolyticus* shall, with respect to its content in units of gas-gangrene antitoxin (histolyticus) conform with paragraphs 4, 5 and 6.

(I) PROVISIONS APPLICABLE TO ANTIPNEUMOCOCCUS SERUM (TYPE I).

1. *Proper Name.*—Antipneumococcus Serum (Type I) is the serum, or the globulins containing the specific immune substances, separated from the blood of animals which have been immunised against cultures of a pneumococcus (*Diplococcus pneumoniæ*) of the variety known as Type I. The proper name of the substance is "(Antipneumococcus Serum Type I)."

2. *Standard Preparation.*—The standard preparation is a quantity of dried antipneumococcus serum (Type I) kept at the National Institute for Medical Research, Hampstead, London.

3. *Quality.*—(1) Antipneumococcus Serum (Type I) shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood or plasma of the immunised animals ; or

(*b*) the solution of the globulins containing the specific immune substances ; or

(*c*) the dried solid prepared from (*i*) the natural serum or (*ii*) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at most, a slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood or plasma without any addition, other than antiseptic, or substraction) shall not contain more than 10 per cent. of total solid matter. A solution of the separated globulins shall not contain more than 20 per cent. of total solid matter.

4. *Strength.*—The potency in units of antipneumococcus serum (Type I) shall be determined, in accordance with a method approved by the Licensing Authority, by comparison of the activity of the serum under test in protecting animals against the lethal action of a virulent culture of *Diplococcus pneumoniæ* (Type I) with the activity under identical conditions of the standard preparation of antipneumococcus serum (Type I).

5. *Unit of Standardisation.*—The unit of antipneumococcus serum (Type I) for the purposes of these Rules is that quantity of the standard preparation which the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container ; and

(*b*) either (*i*) the potency of the preparation expressed as the minimum number of units per c.c. in the case of liquid products or as the minimum number of units per gramme in the case of dry products ; or (*ii*) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package, shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of antitoxic globulins, dried natural serum or dried antitoxic globulins.

(3) The date to be indicated under Rule 109 (3) (*d*) shall not be later than two years after the date of manufacture.

7. *Mixed Antipneumococcus Sera.*—A mixed antipneumococcus serum containing anti-bodies against strains of *Diplococcus pneumonioe* other than those of the variety known as Type I, shall with respect to its content in units of antipneumococcus serum (Type I) conform with paragraphs 4, 5 and 6 of this part of this Schedule.

(J) PROVISIONS APPLICABLE TO ANTIPNEUMOCOCCUS SERUM (TYPE II).

1. *Proper Name.*—Antipneumococcus Serum (Type II) is the serum, or the globulins containing the specific immune substances, separated from the blood of animals which have been immunised against cultures of a pneumococcus (*Diplococcus pneumonioe*) of the variety known as *Type II*. The proper name of the substance is "Antipneumococcus Serum (Type II)."

2. *Standard Preparation.*—The standard preparation is a quantity of dried antipneumococcus serum (Type II) kept at the National Institute for Medical Research, Hampstead London.

3. *Quality.*—(1) Antipneumococcus Serum (Type II) shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood or plasma of the immunised animals ;

or

(*b*) the solution of the globulins containing the specific immune substances ;

or

(*c*) the dried solid prepared from (*i*) the natural serum or (*ii*) the globulins containing the specific immune substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show, at most, a slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood or plasma without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent. of the total solid matter. A solution of the separated globulins shall not contain more than 20 per cent. of total solid matter.

4. *Strength.*—The potency in units of antipneumococcus serum (Type II) shall be determined, in accordance with a method approved by the Licensing Authority by comparison of the activity of the serum under test in protecting animals against the lethal action of a virulent culture of *Diplococcus pneumonioe* (*Type II*) with the activity under identical conditions of the standard preparation of antipneumococcus serum (Type II).

5. *Unit of Standardisation.*—The unit of antipneumococcus serum (Type II) for the purposes of these Rules is that quantity of the standard preparation which the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container ; and

(*b*) either (*i*) the potency of the preparation expressed as the minimum number of units per c.c. in the case of liquid products or as the minimum number of units per gramme in the case of dry products ; or (*ii*) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of antitoxic globulins, dried natural serum or dried antitoxic globulins.

(3) The date to be indicated under Rule 109 (3) (*d*) shall not be later than two years after the date of manufacture.

7. *Mixed antipneumococcus sera.*—A mixed antipneumococcus serum containing antibodies against strains of *Diplococcus pneumonioe* other than those of the variety known as *Type II*, shall, with respect to its content in units of antipneumococcus serum (Type II) conform with paragraphs 4, 5 and 6.

(K) Provisons applicable to Staphylococcus Antitoxin.

1. *Proper Name.*—Staphylococcus antitoxin is the serum, or the antitoxic globulins, separated from the blood of animals which have been immunised against the toxin prepared by artificial culture on suitable media of Staphylococci obtained from cases of infection. The staphylococcus toxin is characterized by its lethal action when injected into susceptible animals, by the production of inflammation and necrosis when injected intracutaneously into susceptible animals, and by its lytic action *in vitro* on the red blood corpuscles of the rabbit. Staphylococcus antitoxin is characterised by its power of neutralizing these activities of the stamphylococcus toxin when mixed with it in effective proportions. The proper name of the substance is " Staphylococcus Antitoxin ".

2. *Standard preparation.*—The standard preparation is a quantity of dried staphylococcus antitoxin kept in the National Institute for Medical Research, Hampstead, London.

3. *Quality.*—(1) Staphylococcus antitoxin shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood or plasma of the immunised animals ; or

(*b*) the solution of the globulins containing the specific immune substances ; or

(*c*) the dried solid prepared from (*i*) the natural serum or (*ii*) the globulins containing the specific immune substances.

(2) If issued in fluid from the liquid shall, at the time of issue, be clear or show, at most a very slight opalescence or precipitate. Preparations of the natural serum (the liquid product of decantation of the coagulated blood or plasma without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent. of solid matter. A solution of the separated antitoxic globulins shall not contain more than 20 per cent. of total solid matter.

4. *Strength.*—(1) The potency in units of staphylococcus antitoxin shall be determined, in accordance with a method approved by the licensing authority and based on the specific neutralising action of the antitoxin under test on a staphylococcus toxin which has been standardised in relation to the standard preparations of staphylococcus antitoxin.

(2) Each container of staphylococcus antitoxin shall contain a sufficient number of units in excess the total minimum of units indicated on the label to ensure that the said minimum total number of units will still be present in the container at the date appearing on the label pursuant to Rule 109 (3) (*d*) as the date up to which the preparation may be expected to retain its potency.

5. *Unit of standardisation.*—The unit of staphylococcus antitoxin for the purposes of these Rules is the specific neutralizing activity for staphylococcus toxin contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

6. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the minimum total number of units in the container ; and

(*b*) either (*i*) the potency of the preparation expressed as the minimum number of units of antitoxin per c.c. in the case of liquid products, or as the minimum number of units of antitoxin per gramme in the case of dryproducts or (*ii*) the total number of c.c. in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, a solution of antitoxic globulins, dried natural serum or dried antitoxic globulins.

(L) PROVISIONS APPLICABLE TO ANTIVENOM SERUM (ANTIVENENE).

1. *Proper Name.*—Antivenom Serum (or antivenene) is the serum or the globulins containing the specific neutralising substances separated from the blood of animals which have been immunized against the venom of one or more poisonous snakes. The proper name of the substance is Antivenom Serum (or antivenene) followed by names of the species of snakes against the venoms of which it has been prepared.

2. *Standard preparations.*—The standard preparations are quantities of the dried venom of the Indian Cobra (*Naia tripudians*), Russel's Viper (*Vipera russellii*) kept at the Central Research Institute, Kasauli.

3. *Quality.*—(1) Antivenom serum (or antivenene) shall be issued for therapeutic use in the form of either—

(*a*) the serum separated from the blood or plasma of immunized animals ; or

(*b*) the solution of the globulins containing the specific neutralizing substances ; or

(*c*) a dry powder prepared from (*i*) the natural serum or (*ii*) the globulins containing the specific neutralising substances.

(2) If issued in fluid form the liquid shall, at the time of issue, be clear or show at most, a very slight opalescence or precipitate. Preparations of the natural

serum (the liquid product of decantation of the coagulated blood without any addition, other than antiseptic, or subtraction) shall not contain more than 10 per cent. of total solid matter. A solution of the separated neutralizing globulins shall not contain more than 20 per cent. of total solid matter.

4. *Strength.*—(1) The potency of antivenom serum (or antivenene) shall be determined in accordance with a method approved by the licensing authority.

5. *Labelling.*—(1) The label on the container shall indicate—

(*a*) the potency of the preparation expressed as the weight of dried venom of each species of poisonous snake against which it is prepared, which is neutralized, under the method of test employed, by one cubic centimeter of the serum;

(*b*) the total number of cubic centimeters in the container.

(2) The label on the container or the label or wrapper on the package shall indicate the nature of the particular product, that is to say, whether natural serum, or a solution of the globulins containing the specific neutralizing substances, or a dried natural serum, or dried globulins.

PART V.-ARSPHENAMINE AND ITS DERIVATIVES.

(A) GENERAL PROVISIONS APPLICABLE TO ARSPHENAMINE AND TO ITS DERIVATIVES.

1. *Standard preparation.*—The standard preparations of arsphenamine and of the derivatives there of are quantities of those preparations kept in the National Institute for Medical Research, Hampstead, London.

2. *Biological tests.*—(1) The tests shall be carried out either—

(*a*) in a central institution appointed by the licensing authority ; or

(*b*) if the licensing authority so direct, in the laboratories of the licensee.

(2) The licensee shall, if the licensing authority so direct, transmit to the appointed institution for testing a sample from each finished batch of arsphenamine, or its derivative, intended for issue. The sample shall consist of at least six sealed containers of the product as completed for issue, taken by random sampling from the whole batch, and each containing at least 0·6 gramme of the product. If the licensing authority direct that the tests shall be carried out in the laboratories of the licensee, they shall be carried out in strict accordance with the directions given by the authority, and in comparison with the standard preparation of arsphenamine or the derivative thereof corresponding to the product under test.

3. The tests shall consist of the following :—

(*a*) *Test for maximum toxicity.*—Several separate containers from each finished batch shall be tested for toxicity by intravenous (or, where the Part of this Schedule relating to a particular derivative requires, by subcutaneous) injection into at least ten mice and five rats, or into such number of animals of some other species as the licensing authority may consider equivalent and no batch shall be passed for issue which shows a toxicity greater than that of the standard preparation when tested under identical conditions. The tests shall be conducted in accordance with such detailed instructions as the licensing authority may issue.

(*b*) *Test for therapeutic potency.*—Samples from each batch shall be tested for therapeutic potency on a series of mice or rats infected with a suitable strain of pathogenic trypanosomes (*T. brucei T. equiperdum, etc.*) in accordance with the following general method and with such detailed instructions as the licensing authority may issue (i) the mice or rats on which the test is made shall be infected with the trypanosome employed to an equal degree, the degree being determined by enumeration per unit volume of blood; (ii) samples from each batch shall be tested by means of several doses each of which shall be administered to at least five of the animals, and the result shall be evaluated by comparison with the effects of the standard preparation, administered to animals of the same species, having the same degree of infection.

4. *Method of issue.*—Arsphenamine and any derivative of arsphenamine shall be issued in the form of a dry powder either in evacuated glass containers or in glass containers which have been filled before being sealed with some inert gas to the exclusion of oxygen unless permission is given by the licensing authority for the issue of a particular derivative in some other form.

(B) Special Provisions applicable to Neoarsphenamine.

1. *Proper Name.*—Neoarsphenamine is the sodium salt of dioxy-diamino arsenobenze-methylene sulphoxylic acid. Its proper name is "Neoarsphenamine".

2. *Quality.*—Neoarsphenamine must have the following physical and chemical characteristics:—

(*a*) the substance must be in the condition of a yellow, dry powder, freely mobile in contact with glass surfaces, and without odour, except such as is due to traces of ether or alcohol;

(*b*) the substance must be soluble in water, but insoluble in absolute ethyl alcohol and in ether. If 0·6 gramme of the substance is added to 1 cubic centimeter of distilled water, it must dissolve rapidly and completely and form a clear, yellow solution, mobile and free from gelatinous particles and suspended matter of every kind;

(*c*) a normal solution of sodium carbonate or a 5 per cent. solution of the anhydrous carbonate, added in equal volume to a 10 per cent. aqueous solution of neoarsphenamine, must not produce a precipitate;

(*d*) diluted hydrochloric acid (B.P.) added in equal volume to a 10 per cent. aqueous solution of neoarsphenamine must give a yellow precipitate of the free acid from neoarsphenamine. If the mixture is warmed, sulphur dioxide must be evolved so as to be detected by iodate-starch paper ;

(*e*) when a solution of 0·2 gramme of neoarsphenamine in 10 c.c. of water is acidified with phosphoric acid and distilled to about one-half its volume formaldehyde must be evolved so as to be detected in the distillate by a red ring formed at the line of contact when five drops of a 1 per cent. solution of phenol is added and a layer of sulphuric acid is run under the mixture ;

(*f*) the dry powder, as taken directly from the ampoules in which it is issued must contain not less than 18 per cent. nor more than 21 per cent. of arsenic as determined by a method approved by the licensing authority.

3. *Test for stability.*—The product as filled into ampoules shall be kept at a temperature of 56° C. for at least 24 hours and shall retain colour, physical properties and solubility substantially unchanged at the end of that period.

(C) SPECIAL PROVISIONS APPLICABLE TO SULPHARSPHENAMINE.

1. *Proper Name.*—Sulpharsphenamine is the sodium salt of dioxy-diamino-arsenobenzene-methy-lene-sulphurous acid. Its proper name is "Sulpharsphenamine".

2. *Quality.*—Sulpharsphenamine must have the following physical and chemical characteristics:—

(*a*) the substance must be in the condition of a yellow, dry powder, freely mobile in contact with glass surfaces, and without odour, except that due to traces of ether or alcohol;

(*b*) the substance must be soluble in water but insoluble in alcohol and in ether. If 0·6 gramme of the substance is added to 1c.c. of distilled water, it must dissolve rapidly and completely, and form a clear, yellow solution, mobile and free from gelatinous particles and suspended matter of every kind;

(*c*) a normal solution of sodium carbonate or a 5 per cent. solution of the anhydrous carbonate, added in equal volume to a 10 per cent. aqueous solution of sulpharsphenamine must not produce a precipitate;

(*d*) five volumes of diluted hydrochloric acid (B.P.) added to one volume of a 10 per cent. aqueous solution of sulpharsphenamine must give, after a few minutes, a yellow precipitate of the free acid from sulpharsphenamine. If the mixture is boiled, sulphur dioxide must be evolved so as to be detected by iodate-starch paper ;

(*e*) when a solution of 0·2 gramme of sulpharsphenamine in 10 c.c. of water is acidified with phosphoric acid and distilled to about one-half its volume, formaldehyde must be evolved so as to be detected in the distillate by a red ring formed at the line of contact when five drops of a 1 per cent. solution of phenol is added and a layer of sulphuric acid is run under the mixture ;

(*f*) on addition of an equal volume of 1 in 10,000 indigo-carmine solution, a 10 per cent. watery solution of sulpharsphenamine must not reduce the indigo-carmine in 5 minutes at 50° C. ;

(*g*) the dry powder, as taken directly from the ampoules in which it is issued, must contain not less than 18 per cent., or more than 21 per cent. of arsenic, as determined by a method approved by the licensing authority.

3. *Test for toxicity and therapeutic potency.*—The test of maximum toxicity and for therapeutic potency prescribed in paragraph 2 (3) of Section (A) of this Part of this Schedule shall, in the case of sulpharsphenamine, be carried out by subcutaneous injection into mice or rats.

4. *Test for stability.*—The products as filled into ampoules shall be kept at 56° C. for at least 24 hours and shall retain its colour, physical properties and solubility substantially unchanged at the end of that period.

(D) SPECIAL PROVISIONS APPLICABLE TO DERIVATIVES OF ARSPHENAMINE OTHER THAN THOSE SPECIFIED IN (B) AND (C) OF THIS PART.

1. *Nature of substance.*—In the case of any derivative of arsphenamine other than those specified in Sections (B) and (C) of this Part of this Schedule the applicant for a manufacturing or an import licence shall submit to the licensing authority with his application a statement of the true, chemical nature and composition

of the derivative, and a full and detailed account of the chemical tests by which that composition is determined and by which the uniformity of successive batches is secured.

2. *Proper name.*—The applicant shall also submit with his application the name which he proposes to use for the derivative to which the application relates, and such name, if approved by the licensing authority, may be used as the proper name of the derivative.

3. *Chemical tests.*—If a licence is granted for the manufacture of such a derivative of arsphenamine the licensee shall carry out on each batch of the derivative such, if any, of the chemical tests submitted with the application as are accepted by the licensing authority, and any others which the authority, may direct as requisite for determining the composition and securing its uniformity. No batch of the derivative which fails to pass any of the tests so accepted or directed shall be issued.

4. *Tests for toxicity and potency.*—Each batch of such derivative shall further be tested, by biological methods, for toxicity and potency, according to the methods prescribed in Section (A) of this Part of this Schedule. In the event of no standard preparation being available for a part cular derivative, the tests shall be made in such form and their results interpreted in accordance with such criteria as the licensing authority may direct.

PART VI.—INSULIN.

1. *Proper name.*—Insulin is the preparation of the specific antidiabetic principle of the pancreas. Its proper name is "Insulin".

2. *Special conditions of licence.*—It shall be a condition of every licence to manufacture or to import insulin :—

(*a*) that it shall not be issued in a mixture with any other therapeutic agent except with the previous consent of the licensing authority;

(*b*) that if issued for injection suspended in some medium in which it is not itself soluble, it shall be tested before suspension.

3. *Standard preparation.*—The standard preparation is a quantity of dry soluble insulin hydrochloride prepared and kept in the National Institute for Medical Research, Hampstead, London.

4. *Unit of Standardisation.*—The unit of insulin for the purposes of these Rules is the specific activity contained in such an amount of the standard preparation as the Medical Research Council in the United Kingdom may from time to time indicate as the quantity exactly equivalent to the unit accepted for international use.

5. *Quality.*—The acidity of the prepared watery solution, as determined by a suitable indicator, shall be such that the hydrogen-ion concentration is not less than that corresponding to pH=4, or greater than that corresponding to pH=3.

6. *Tests.*—(1) The methods used for testing the potency of preparations in comparison with the standard preparation shall be such as the licensing authority may from time to time approve.

(2) In addition, samples from each batch shall be tested in such manner as the licensing authority may direct for the purpose of ascertaining its stability under ordinary conditions of storage.

7. *Container.*—In the case of a prepared solution of insulin the glass of the container shall be non-alkaline resistance glass.

8. *Labelling.*—In the case of prepared solution of insulin the label on the container shall indicate strength as the number of units per c.c., and in the case of compressed tablets as the number of units in each tablet.

PART VII.—PITUITARY (POSTERIOR LOBE) EXTRACT.

1. *Proper name.*—Pituitary extract is the watery extract prepared from the separated posterior lobe of the pituitary body, or the watery solution of one or more of the separated active principles of that lobe. The proper name of the complete water extract is "Pituitary (posterior lobe) Extract". The proper name of a solution containing one of the separated active principles is "Oxytocic principle of the pituitary posterior lobe" or "Pressor principle of the pituitary posterior lobe" or such other name descriptive of such a solution as the licensing authority may in any particular case approve in writing.

2. *Standard preparation.*—The standard preparation is a quantity of dried acetone-extracted substance obtained from the posterior lobes of fresh pituitary bodies of oxen. This standard is kept in the National Institute for Medical Research, Hampstead, London.

3. *Unit of standardisation.*—(1) The unit of pituitary extracts for the purposes of these Rules is the specific activity corresponding to that yielded by 0·5 milligramme of the standard preparation when extracted by the method approved by the licensing authority under this Part.

(2) When the preparation is a solution of a separated active principle, the unit employed in indicating the strength shall be the amount of that active principle yielded to extraction by 0·5 mgm. of the standard preparation as determined by the appropriate biological test.

4. *Quality.*—The acidity of the prepared watery extract shall be such that the hydrogen-ion concentration is not less than that corresponding to pH=4, or greater than that corresponding to pH=3.

5. *Tests.*—(1) The method used for preparing the extract from the standard preparation and for its use in a comparative biological test and the biological methods employed in making the test shall be such as the licensing authority may from time to time approve.

(2) Samples from each batch of the finished product shall be tested for sterility in accordance with the methods set forth in Part X of the Rules unless the finished product has been sterilized by heat in a manner satisfactory to the licensing authority after being sealed in the containers.

6. *Container.*—The glass for the container shall be non-alkaline resistance glass.

7. *Labelling.*—The label on the container shall indicate the strength of the extract as the number of units per c.c.

8. The date to be specified in compliance with the requirements of Rule 109 (3) (*d*) shall be such date as the licensing authority shall in any particular case have approved in writing.

PART VIII.—LIQUOR ADRENALINAE HYDROCHLORIDI B. P. FOR PARENTERAL ADMINISTRATION.

Proper name.—Liquor Adrenalinae Hydrochloridi is a sterile solution of adrenaline in normal saline and hydrochloric acid, containing in each 100 c.c. not less than 0·09 gramme and not more than 0·110 gramme C_9 H_{13} O_3 N.

Standard Preparation.—The standard preparation is a quantity of adrenaline B.P. which satisfies all the tests for purity specified in the British Pharmacopoeia. The optical rotation of a 4 per cent. w/v solution of standard Adrenaline in N/1 hydrochloric acid, should be between—50 and—53 degrees.

Test for potency.—A suitable solution of adrenaline hydrochloride injected intravenously into a cat or a dog by the methods described below produces a rise in the systolic blood-pressure of the animal corresponding to that produced by an equal amount of a solution of adrenaline B.P.

(*i*) *Preparation of the solution for the test.*—The following method is suggested :—Weight accurately about 0·050 gramme of standard adrenaline, dissolve it in 5 c.c. of N/10 hydrochloric acid and dilute this to 50 c.c. by the addition of distilled water, thus making a 1 in 1,000 solution. This solution must be recently prepared, otherwise it deteriorates. It will keep for a short time if preserved in hard glass containers in a refrigerator, but it must be discarded if any signs of deterioration, such as dis-colouration are observed.

Suitable dilutions of the standard adrenaline solution may then be made in physiological saline for comparison with equivalent dilutions of Liquor Adrenalinae Hydrochloridi to be tested.

(*ii*) *Methods of Comparison of Potency.*—Either of the following methods may be adopted :—

(A) For the purpose of the assay a full grown cat, preferably male, should be used. The cat should be anaesthetised with a suitable anaesthetic, the spinal chord should be divided and the brain destroyed, the respiration being maintained artificially. The blood-pressure is estimated by inserting a cannula into the carotid artery and connecting the same with a mercury manometer which records on a moving drum. The injections are made into the exposed femoral vein. The blood-pressure must be low and must not vary before experiments are started.

Determine the amount of standard solution necessary to cause a sub-maxima rise in blood-pressure by injecting intravenously varying doses of the solution at regular intervals and after a satisfactory dose has been ascertained, the uniformity of reaction should be tested by the injection of two or more doses of equal size. If these injections produce approximately equal increases in blood-pressure alternative injections of the solution to be tested and of the standard are made carrying the amount of the unknown until two or more successive injections raise the blood-pressure to the same height indicating that the amount of active agent is the same in the doses used. From the results thus obtained, the strength of the unknown solution may be determined and adjusted.

(B) For the purpose of the assay, a dog of medium size should be used. The animal should be anaesthetised with a suitable anaesthetic and maintained under artificial respiration. It is prepared for blood-pressure estimations by inserting

a cannula into the carotid artery and connecting the same with a mercury manometer with records on a moving drum. The injections are made into the exposed femoral vein. Before the test is made, in case any mascular movement such as twitching is present, the dog should receive by intravenous injection in sufficient dose of curare, but if the animal is deeply anaesthetised this is not necessary. The dog should also receive a sufficient dose of atropine sulphate (from 0·001 gramme to 0·002 gramme) to paralyse the vagi, this paralysis being proved by electrical stimulation. Injections must be made at regular intervals of approximately 5 minutes.

Determine the amount of standard solution necessary to cause a rise in blood-pressure from 30 to 60 mm. of mercury by injecting intravenously varying doses of the solution and after a satisfactory dose has been ascertained, the uniformity of reaction should be tested by the injection of two or more doses of equal size. If these injections produce approximately equal increases in blood-pressure alternate injections of the solution to be tested and of the standard are made varying the amount of the unknown until two or more successive injections raise the blood pressure to the same height indicating that the amount of active agent is the same in the doses used. From the results thus obtained, the strength of the unknown solution may be determined and adjusted.

Containers.—Ampoules shall be made of white resistance glass passing the B.P. tests for limits of alkalinity of glass. Containers other than ampoules shall be made of amber coloured resistance glass passing the B.P. tests for limits of alkalinity of glass.

Storage.—Liquor Adrenalinae Hydrochloridi shall be kept in small, well filled, well-closed, bottles or ampoules, protected from light. If the solution becomes brown in colour or contains a precipitate, it must be rejected. A suitable preservative may be added to the solution.

Labelling.—The label of the container shall contain the following in addition to any other particulars prescribed in these rules :—

1. Strength of the solution.
2. The word "sterile" or "suitable for parenteral injection."
3. Dose (0·12 to 0·5 mil. by injection).
4. Caution.—If the solution is brown in colour or contains a precipitate it must be rejected.

PART IX.—Any other preparations in a form to be administered parenterally.

Tests.—1. The preparation shall be in a container which precludes the access of bacteria.

2. The composition of the preparation shall be in accordance with the composition stated on the label. Such deviations as may be allowed in the composition of the preparation shall be fixed by the Licensing Officer.

3. The preparation shall comply with tests for sterility.

4. If the container is made of glass, the glass shall pass the tests for limit of alkalinity in glass laid down in the British Pharmacopoeia.

PART X.—SURGICAL LIGATURE AND SURGICAL SUTURE.

1. *Proper Name.*—Surgical ligature or suture is any ligature or form of binding material prepared from the gut or any tissue of an animal and offered or intended to be offered for sale for use in surgical operation upon the human body. Where such ligature or suture is offered or intended to be offered for sale as sterile and ready for use the proper name of the substance shall be "sterilized surgical ligature or sterilized surgical suture" followed, in brackets, by the accepted scientific name or a title descriptive of the true nature and origin of the substance as, for example :—"sterilized surgical ligature (catgut)" or "sterilized surgical suture (horsehair)."

2. *Test of Sterility.*—Every batch of surgical ligature (suture) shall consist entirely of material collected under uniform conditions and simultaneously subjected or intended to be subjected to the same process or series of processes for rendering it sterile.

3. A sample of surgical ligature (suture) shall be taken from each batch consisting of not less than 1 per cent. of the whole quantity of material constituting the batch. The sample shall, when practicable, be the contents of at least one whole container or packet, and shall be drawn at random from the whole number of containers or packets constituting the batch.

4. The sample shall be subjected to the following processes for testing its sterility :—

(*a*) the container or packet shall be opened and the sample removed with aseptic precautions ;

(*b*) after all the adherent fluid has been drained off as completely as possible, the sample shall be placed entire in a test tube at least 3·5 cms. in diameter and 17·5 cms. in length and containing 50 mils. of sterile distilled water. This tube shall then be closed by some method which will preclude the access of bacteria, and be placed in an incubator at 37°C. for 24 hours.

(*c*) after this incubation, the sample shall be aseptically transferred to a similar tube containing a solution of 1 per cent. of sodium thiosulphate and 1 per cent. of crystallised sodium carbonate in distilled water, the tube and solution having been previously sterilized in the autoclave. In this solution the sample shall again be incubated for 24 hours at 37°C.

(*d*) after the second in cubation the sample shall be again removed aseptically and, without further washing, shall be examined for the presence of living bacteria and their spores.

The sterility tests shall be carried out either (*i*) by the method prescribed in Rules 117 (1), (2), (3) and 118 (1) ; or (*ii*) by placing the sample in a tube at least 3·5 cms. in diameter and 17·5 cms. in length containing not less than 50 mils. of a culture medium prepared by dissolving 0·2 per cent. of prepared agar-agar in a nutrient bacteriological broth*, the mixture being sterilized in the autoclave :

**Note.*—The broth may preferably be made by the digestion of meat with tryinps Dougla's broth or Hartly's modification thereof.

Provided that, if a manufacturer satisfies the licensing authority that he has already in use tests for the presence of living aerobic or anaerobic bacteria, and that these tests, as applied by him, will detect the presence of such bacteria in the ligature (suture) as ready for issue with a certainty at least equal to that afforded by the application of the tests prescribed in the abovementioned articles, the licensing authority may approve the use of such tests in the place of the tests so prescribed ; but, in that event, the authority may at any time withdraw such approval and require the manufacturer to carry out the prescribed tests ;

(*e*) the tubes of culture medium containing the sample shall be incubated at 37°C for 12 days, and examined daily for the growth of bacteria ;

(*f*) if no such growth is detected during this period, the batch from which the sample was drawn shall be treated as free from living bacteria and their spores, and as having passed the test :

Provided that, if a licensee satisfies the licensing authority that the tests prescribed in sub-paragraph (*c*) of this paragraph for freeing substances from combined or adherent antiseptics are not suitable for application to the substance which he is licensed to manufacture or import, the licensing authority may approve in writing the application of alternative tests in place of the tests so prescribed.

Labelling.—For the purpose of Rule 109 (3) (*b*) the date on which the manufacture of the batch is completed shall be the date on which the test for sterility was completed.

PART XI.—Provisions applicable to the production of Bacteriophages.

1. *Definitions* :—

(*i*) This part of this Schedule applies to the bacteriophages made from any micro-organism Pathogenic to man or other animal.

(*ii*) For the purpose of this part of this schedule a bacteriophage means a sterile preparation derived from a culture of the micro-organism from which the bacteriophage derives its name.

2. *Staff of establishment.*—Any establishment where bacteriophages are prepared must be under the complete direction and control of a competent expert in bacteriology, who must be assisted by a staff adequate for carrying out the tests required during the preparation of the bacteriophages and in connection with the finished products.

3. *Proper name.*—The proper name of any bacteriophage shall be the word 'Bacteriophage' followed by the name of the micro-organism from which it is prepared, or other name approved by the licensing authority.

4. *Records.*—Cultures used in the preparation of bacteriophage must before being manipulated into a bacteriophage be identified by the generally accepted tests applicable to the particular micro-organism. The permanent records which the licensee is required to keep shall include a record of the origin, properties and characteristics of the cultures.

5. *Combined bacteriophages.*—Bacteriophages may be issued either singly or combined in the same container. In the case of combinations of bacteriophage a name for the combined bacteriophage may be submitted by the licensee to the licensing authority and, if approved, may be used as a proper name of the bacteriophage.

6. *Containers.*—The container shall be sealed glass ampoule of non-alkaline resistance glass.

7. *Labelling.*—The label of the container shall indicate :—

(*a*) The proper name of the bacteriophage ;

(*b*) The words "For oral administration only" ;

(*c*) The date of manufacture ; and

(*d*) A caution to the effect that if the preparation is cloudy or shows a deposit it should be discarded.

8. *Tests.*—Bacteriophages shall be subjected to the same tests for sterility as prescribed in these rules for bacterial vaccines.

PART XII-A.—The Digitalis Group of Drugs and Ergot and its Derivatives.

1. *Proper names, etc.*—The proper names, standard preparations, units of standardisation, quality and method of storage of drugs belonging to the digitalis group and of ergot and its derivatives shall be those specified in the British Pharmacopoeia.

2. *Tests.*—Drugs belonging to the digitalis group and ergot and its derivatives shall be submitted to the tests described in the British Pharmacopoeia.

B.—Fish-liver oils.

1. *Units of standardisation.*—The units of standardisation for vitamin preparations shall be those specified in the British Pharmacopoeia.

2. *Tests.*—Fish-liver oils and other vitamin preparations shall be submitted to one of the tests for activity specified in the British Pharmacopoeia.

C.—Liquor Adrenalinae Hydrochloridi not to be administered parenterally.

These preparations shall be submitted to the test prescribed in Part VIII of this Schedule except that they will not be tested for sterility. The label on the container and the label or wrapper on the package shall bear the words "Not to be injected" clearly printed in a distinctive manner in addition to any particulars prescribed in these Rules.

D.—Preparations containing any vitamins in a form not to be administered parenterally.

Definition.—Vitamins include natural and synthetic Vitamins, synthetic derivatives of Vitamins, Vitamin esters and synthetic substances having physiological actions comparable with those of the aforementioned substances and natural products containing Vitamins.

Units of Standardisation.—The units of standardisation for Vitamin preparations shall be those specified in the British Pharmacopoeia.

Tests.—Drugs containing Vitamins shall be submitted to the tests for Vitamins prescribed in the British Pharmacopoeia or the United States Pharmacopoeia.

Labelling.—1. The number of units and/or the actual weight of each vitamin per unit volume and/or weight shall be declared on the label.

2. The label on the container and the label or wrapper on the package shall bear the words "Not to be injected" clearly printed in a distinctive manner in addition to any other particulars prescribed in any other Rule.

E.—PREPARATIONS CONTAINING LIVER EXTRACT IN ANY FORM NOT TO BE ADMINISTERED PARENTERALLY.

Tests.—Drugs containing liver extract shall be submitted to the tests prescribed in the British Pharmacopoeia or the United States Pharmacopoeia.

Labelling.—The label on the container and the label or wrapper on the package shall bear the words "Not to be injected" clearly printed in a distinctive manner in addition to any particulars prescribed in any other Rule.

F.—PREPARATIONS CONTAINING HORMONES IN ANY FORM NOT TO BE ADMINISTERED PARENTERALLY.

Definition.—Hormones include natural and synthetic Hormones, synthetic derivatives of Hormones, Hormone esters and synthetic sub-glandular products containing Hormones.

Tests.—Drugs containing Hormones shall be submitted to the tests prescribed in the British Pharmacopoeia or the United States Pharmacopoeia or by the licensing authority if any particular Hormone is not included in the British Pharmocopoeia or the United States Pharmacopoeia.

Labelling.—The label on the container and the label or wrapper on the package shall bear the words "Not to be injected" clearly printed in a distinctive manner in addition to any particulars prescribed in any other Rule.

PART XIII.—GENERAL.

1. For the purposes of this Schedule, any test or method of testing described in the British Pharmacopoeia shall be deemed to be a method approved by the licensing authority.

2. The licensing authority shall publish in the official Gazette from time to time particulars of any test or method of testing approved by him.

SCHEDULE G.

(*See* Rule 97.)

Allylisopropylacetylurea ;

Insulin ;

Phenylethylhydantion ; its salts ; its acyl derivatives ; their salts ;

Pituitary gland, the active principles of ;

Thyroid gland, the active principles of ; their salts.

SCHEDULE H.

[*See* Rule 65 (9) and (11).]

Substances required to be sold by retail only upon a prescription given by a registered medical practitioner.

Amidopyrine ; its salts.

Barbituric acid ; its salts ; derivatives of barbituric acid ; their salts ; compounds of barbituric acid, its salts, its derivatives, their salts, with any other substance : provided that compounds, the barbituric acid content of which does not exceed 50 milligrams in a single therapeutic dose shall be exempted.

Dinitrocresols ; dinitronaphthols ; dinitrophenols ; dinitrothymols.

Para-aminobenzene-sulphonamide ; its salts ; derivatives of para-aminobenzene-sulphonamide having any of the hydrogen atoms of the para-amino group or of the sulphonamide group substituted by another radical ; their salts. But excluding preparations and dressings containing these and intended for external use.

Phenylcinchoninic acid ; Salicylcinchoninic acid ; their salts, their esters ;

Sulphonal ; alkylsulphonals.

SCHEDULE I.

[*See* Rule 101 (4).]

Particulars as to proportion of poison in certain cases.

Name of Poison.	Particulars.
Alkaloids—	
Aconite, alkaloids of ...	... The proportion of any one alkaloid of aconite that the preparation would be calculated to contain on the assumption that all the alkaloids of aconite in the preparation were that alkaloid.
Belladonna, alkaloids of Calabar bean, alkaloids of Cocoa, alkaloids of Ephedra, alkaloids of Ergot, alkaloids of Gelsemium, alkaloids of Jaborandi, alkaloids of Lobelia, alkaloids of Pomegranate, alkaloids of Solanaceous, alkaloids not otherwise included in Schedule E Stavesacre, alkaloids of Veratrun, alkaloids of Yohimba, alkaloids of	... The same as above, with the substitution for the reference to aconite of a reference to belladonna, calabar bean or such other of the said poisons as the case may require.
Antimonial poisons ...	... The proportion of antimony trioxide ($SB_2 O_3$) or antimony pentoxide ($SB_2 O^5$) that the preparation would be calculated to contain on the assumption that the antimony (Sb) in the poison had been wholly converted into antimony trioxide or antimony pentoxide, as the case may be.

Name of Poison.	Particulars.
Arsenical poisons	The proportion of arsenic trioxide (As_2O_3) or arsenic pentoxide (As_2O_5) that the preparation would be calculated to contain on the assumption that the Arsenic (As) in the poison had been wholly converted into arsenic trioxide or arsenic pentoxide as the case may be.
Barium, salts of	The proportion of one particular barium salt which the preparation would be calculated to contain on the assumption that the barium (Ba) in the poison had been wholly converted into that salt.
Digitalis, glycosides of; other active principles of digitalis.	The number of units of activity as defined in the *British Pharmacopoeia* contained in a specified quantity of the preparation.
Hydrocyanic acid; cyanides; double cyanides of mercury and zinc.	The proportion of hydrocyanic acid (HCN) that the preparation would be calculated to contain on the assumption that the cyanides in the poison had been wholly converted into hydrocyanic acid.
Lead, compounds of, with acids from fixed oils.	The proportion of lead oxide (PbO) that the preparation would be calculated to contain on the assumption that the lead in the poison had been wholly converted into lead oxide.
Mercury- organic compounds of ...	The proportion of organically combined mercury (Hg) contained in the preparation.
Phenols	The proportion of phenols (added together) contained in the preparation.
Compounds of phenol with a metal.	The proportion of phenols (added together) that the preparation would be calculated to contain on the assumption that the compound of phenols with a metal had been wholly converted into the corresponding phenols.

Name of Poison.	Particulars.
Pituitary gland, the active principles of.	Either— (*a*) the number of units of activity as defined in the *British Pharmacopœia* contained in a specified quantity of the preparation ; or (*b*) the proportion of pituitary gland, or of anterior or of posterior lobe of the gland, as the case may be, contained in the preparation ; or (*c*) the amount of pituitary gland, or of anterior or of posterior lobe of the gland, as the case may be, from which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or to dried gland substance.
Potassium hydroxide ...	The proportion of potassium monoxide (K_2O) which the preparation would be calculated to contain on the assumption that the potassium hydroxide in the preparation had been wholly converted into potassium monoxide.
Sodium hydroxide	The proportion of sodium monoxide (Na_2O) which the preparation would be calculated to contain on the assumption that the sodium hydroxide in the preparation had been wholly converted into sodium monoxide.
Strophanthus, glycosides of ...	The amount of Standard Tincture of Strophanthus as defined in the *British Pharmacopœia* which possesses the same activity as a specified quantity of the preparation when assayed by the method described in the said *Pharmacopœia*.
Suprarenal gland, the active principles of ; their salts.	Either— (*a*) the proportion of suprarenal gland or of the cortex or of the medulla of the gland, as the case may be, contained in the preparation ; or (*b*) the amount of suprarenal gland or of the cortex or of the medulla of the gland, as the case may be, from which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or dried gland substance.

Name of Poison.	Particulars.
Thyroid gland, the active principles of; their salts.	Either— (*a*) the proportion of thyroid gland contained in the preparation; or (*b*) the amount of thyroid gland from which a specified quantity of the preparation was obtained together with an indication whether the amount relates to fresh or dried gland.

SCHEDULE J.

[*See* Rule 106.]

Diseases and ailments (by whatever name described) which a drug may not purport or claim to prevent or to cure.

Blindness.
Bright's disease.
Cancer.
Cataract.
Deafness.
Delayed Menstruation.
Diabetes.
Epilepsy.
Female Diseases (in general).
Fevers (in general).
Fits.
Glaucoma.
Goitre.
Gonorrhœa.
Heart Diseases.
High Blood Pressure.
Hydrocele.
Infantile Paralysis.
Leprosy.
Leucoderma.
Lockjaw.
Locomotor Ataxia.
Lunacy.
Lupus.
Obesity.
Paralysis.
Plague.
Rupture.
Sexual impotence.
Small-pox.
Soft Chancre.
Syphyllis.
Tuberculosis.
Tumours.
Venereal Diseases (in general).

SCHEDULE K

[*See* Rule 123.]

Class of drugs.	Extent and conditions of exemption.
1. Substances not intended for medicinal use.	All the provisions of Chapter IV of the Act and the rules thereunder, subject to the condition that the drug is not sold for medicinal use or for use in the manufacture of medicines and does not purport to comply with the standard set out in the Schedule to the Act.
2. * * *	* * * *
2A. Quinine and other Anti-Malarial drugs.	The provisions of clause (*c*) of section 18 of the Act. (If the drugs are sold in retail under the arrangements made by the State Government for the sale and distribution of drugs.)

Class of drugs.	Extent and conditions of exemption.
3. Biological and other special products specified in Schedule C, intended to be used solely for veterinary purposes.	All the provisions of Chapter IV of the Act and the rules thereunder, subject to the condition that each container shall bear a label indicating that the substance is for veterinary use only.
4. Patent or proprietary medicines intended to be used solely for veterinary purposes.	All the provisions of Chapter IV of the Act and the rules thereunder, subject to the condition that the description on the label or the container shall indicate that the medicine is intended for administration to animals.
5. Drugs supplied by a registered medical practitioner to his own patient, or any drug specified in Schedule C supplied by a registered medical practitioner at the request of another such practitioner if it is specially prepared with reference to the condition and for the use of an individual patient provided the registered medical practitioner is not (*a*) keeping an open shop or (*b*) selling across the counter or (*c*) engaged in the importation, manufacture, distribution or sale of drugs in India* to a degree which renders him liable to the provisions of Chapter IV of the Act and the rules thereunder and drugs supplied by a hospital or dispensary maintained or supported by Government or a local body or by charity or voluntary subscription.	All the provisions of Chapter IV of the Act and the rules thereunder, subject to the condition that in the case of a medicine containing a substance specified in Schedule E— (*a*) the medicine shall be labelled with the name and address of the institution by which, or the registered medical practitioner by whom, it is supplied ; (*b*) if the medicine is for external application, it shall be labelled with the words "Poison. For external use only", or, if it is for internal use with the dose ; (*c*) the name of the medicine or ingredients of the preparation and the quantities thereof, the dose prescribed the name of the patient and the, date of supply and, in the case of medicine supplied by a hospital or dispensary, the name of the person who gave the prescription shall be entered at the time of supply in a register to be maintained for the purpose ; (*d*) the entry in the register shall be given a number and that number shall be entered on the label of the container ; (*e*) the register and the prescriptions, if any, on which the medicines are issued, shall be preserved for not less than two years from the date of the last entry in the register or the date of the prescription, as the case may be.

*"India" means the territory of India excluding the State of Jammu and Kashmir [*vide* s. 3 (*bb*) of Act XXIII of 1940].

Class of drugs.	Extent and conditions of exemption.
6. Medicine supplied by a veterinary hospital or by a veterinary surgeon.	All the provisions of Chapter IV of the Act, and the rules thereunder subject to the condition that in the case of a medicine containing a substance specified in Schedule E, the container shall bear a label indicating that the medicine is intended for animal treatment.
7. Quinine sulphate	The provisions of sub-section (*a*) (*i*) of Section 18 of the Act to the following extent :— (*i*) the colour of the drug may be pink, owing to its being coloured with an edible pink colouring matter ; (*ii*) the B. P. tests for readily carbonisable substances produce a yellow colour of an intensity about four times the colour produced with quinine sulphate conforming to the B. P. standard ; (*iii*) other Cinchona alkaloids present, shall not exceed 6 per cent. ; and (*iv*) the residue on incineration shall not exceed 0·14 per cent.
8. Medicine prepared in accordance with and intended solely for the treatment of patients under the Homoeopathic system of medicine.	All the provisions of Chapter IV of the Act and the Rules thereunder subject to the condition that a container containing such drugs shall bear a label " Homoeopathic Medicine ".

Rule 1 (3)

G. N., G. D., No. 4121/33 (3), dated 27th March 1947 (B. G., Pt. I, p. 103).

In pursuance of sub-rule (3) of rule 1 of the Bombay Drugs Rules, 1946, the Government of Bombay is pleased to appoint the 1st April 1947 as the date on which the said rules shall come into force.

Rule 1 (8)

G. N., H. & L. G. D., No. 4121/33 (b), dated 28th October 1948 (B. G., Pt. IV-A, p. 412).

In pursuance of sub-rule (3) of rule 1 of the Bombay Drugs Rules, 1946, and in partial modification of the Government Notification in the General Department, No. 4121/33 (3), dated the 26th March 1947, the Government of Bombay is pleased to appoint the 1st April 1949 as the date on which sub-rules (1) and (3) of rule 103 of the Bombay Drugs Rules, 1946, shall come into force.